

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ) 2:12-md-02342-CMR  
)  
ZOLOFT (SERTRALINE ) September 2, 2015  
HYDROCHLORIDE) PRODUCTS ) A.M. SESSION  
LIABILITY LITIGATION ) 10:05 a.m.-12:49 p.m.  
J. RETTENMAIER USA LP ) Philadelphia, PA

DAUBERT HEARING  
BEFORE THE HONORABLE CYNTHIA M. RUFÉ

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I N D E X

WITNESS	DIRECT	CROSS	REDIRECT	RECROSS
Nicholas Jewell		3		

1 P R O C E E D I N G S

2 THE CLERK: All rise.

3 (Call to Court)

4 THE COURT: Good morning, everyone.

5 ALL: Good morning, Your Honor.

6 THE COURT: Please be seated. Did we  
7 give everyone a chance to set up the electronics and  
8 everything else?

9 MS. YATES: I believe so, Your Honor.

10 THE COURT: All right. Dr. Jewell.

11 MR. ZONIES: Your Honor, may I approach  
12 with --

13 THE COURT: Oh, yes, thank you, Mr.  
14 Zonies. Dr. Jewell, please resume the stand. Thank  
15 you. Good morning.

16 THE WITNESS: Good morning.

17 THE COURT: All right. You remain  
18 under oath, Dr. Jewell. Please be seated. Ms. Yates,  
19 cross-examination, please.

20 MS. YATES: Thank you, Your Honor.

21 CROSS-EXAMINATION

22 BY MS. YATES:

23 Q. Good morning, Dr. Jewell. Nice to meet you.

24 A. Good morning.

25 Q. Doctor, I wanted to start by talking a

1 little bit about overlapping populations. And I'd  
2 like to start our conversation to see if you agree  
3 that if one study is a subset of another study,  
4 there's really only one study to consider, correct?

5 A. Well, it depends on the context of the  
6 question. If, as we were discussing yesterday, one  
7 study is subsumed in another because a second study  
8 follows a new set of women for a new set of years,  
9 then there's no -- the information in the first study  
10 is entirely contained in the second. But on the other  
11 hand, as I discussed yesterday, there's still interest  
12 in seeing if the information from an earlier period of  
13 time is confirmed by independent information in the  
14 same population at a different point or different  
15 interval in time.

16 Q. Let me be a little more specific, Doctor.  
17 I'm specifically referring to the two Swedish studies,  
18 Callen and Reis Callen (ph), 2010 -- 2007 and 2010,  
19 Doctor, and you have previously testified that Callen  
20 2007 is a subset of Reis Callen 2010 and there's  
21 really only one study to consider, correct?

22 A. Yes, in that case, in the Swedish case, one  
23 is completely subsumed in the other.

24 Q. Okay.

25 A. As I just described here.

1 MS. YATES: And, Your Honor, may I move  
2 around again.

3 THE COURT: Yes.

4 MS. YATES: Thank you.

5 BY MS. YATES:

6 Q. And I think, Doctor, sorry, this is what  
7 we're referring to, right, that Callen is a complete  
8 subset of Reis-Callen, and those are the two studies  
9 we're specifically referring to, correct?

10 A. I pronounce it Collin, but --

11 Q. And I think Collin pronounces it even more  
12 complicated, okay.

13 Okay. Let's move from Sweden, Doctor, to  
14 Denmark and I think we have your graphics up, by the  
15 way if I -- is it better if I pull this a little  
16 further forward?

17 A. Sure.

18 Q. I think this is your graphic on the three  
19 Danish studies, Doctor, Cornum, Pedersen and Jimenez-  
20 Solem; is that correct?

21 A. That is correct.

22 Q. All right. And you testified a little bit  
23 yesterday about these studies, and you do agree, sir,  
24 that certainly there are some overlap in these  
25 populations, correct?

1 A. Absolutely.

2 Q. Now, yesterday you said that Cornum was the  
3 first step, and that -- and that's four counties,  
4 right?

5 A. Well, I actually misspoke I think yesterday.  
6 I think Pedersen's paper predates the Cornum paper.

7 Q. Correct, you did misspeak yesterday.

8 A. The order is Pedersen followed by Cornum,  
9 followed by Jimenez-Solem.

10 Q. Right. So when yesterday you said Cornum  
11 was the first step, but Pedersen tried to replicate.

12 A. The other way around.

13 Q. You were wrong.

14 A. It was the other way around, yes.

15 Q. Well, so Pedersen was the entire country and  
16 then Cornum was just four counties.

17 A. That is correct.

18 Q. Okay. Now, let's take a little look.  
19 Cornum covers 1991 through 2007, correct?

20 A. That looks roughly right from the graphic,  
21 yes.

22 Q. Yeah, it's a little late on dates, isn't it,  
23 Doctor, it's a little closer to 1990. If we divide  
24 that area in five, it's probably closer to here,  
25 right, if we divide it in five? '91, '92, '93, '94,

1 fair? So we go a little too long on your chart,  
2 right?

3 A. I can't remember, if I went back to the  
4 original paper if it was 1991 or 1990. That looks  
5 like 1990 there from the graphics.

6 Q. Well, should we -- would you like to check  
7 Cornum, do you have your binder of studies?

8 A. I do, yeah, I'd be happy to.

9 Q. Let's check Cornum.

10 MS. YATES: And, Your Honor, I have  
11 another binder of studies that I don't know if it's  
12 identical to Dr. Jewell's, so if I may provide the  
13 Court one and the witness, just so we're on the same  
14 page.

15 THE COURT: You certainly may.

16 MS. YATES: Just in case there's one  
17 not in the binder. Thank you.

18 THE WITNESS: Okay.

19 BY MS. YATES:

20 Q. Can you confirm that Cornum is actually  
21 1991?

22 A. Yes, 1991 I think to 2007.

23 Q. Right.

24 A. So that green line, I'm happy to move it  
25 over a little bit, if you would like.

1 Q. A little too far over, right? It doesn't  
2 cover 1990.

3 A. It doesn't, apparently not.

4 Q. Okay. Pedersen is 1996 to 2003.

5 A. I'd have to check but that's approximately  
6 what I remember.

7 Q. Okay. And Jimenez-Solem 1997 to 2009,  
8 correct?

9 A. I'd have to check, but that sounds  
10 reasonable according to my memory.

11 Q. Doctor, if you want to check.

12 A. It's up to you. I don't mind checking if  
13 you like, but I'd had to take your word for it.

14 Q. Okay. All right. So you will agree, sir,  
15 that for the years 1996 to 2003, Cornum is a subset of  
16 Pedersen, right?

17 A. Correct. And the Cornum covered just a  
18 geographic region of Denmark and Pedersen had the  
19 whole national registry at that point.

20 Q. Right. So we've got a subset in that  
21 section, right?

22 A. Correct.

23 Q. And so there's no new data under the Reis,  
24 Callen-Reis analogy, that's overlap, correct?

25 A. Sorry, I didn't --



1 Q. For those years?

2 A. I don't understand your question.

3 Q. These two studies, Cornum is a subset of  
4 Pedersen for these years.

5 A. For those specific years, yes, but Cornum  
6 has these additional years as you've pointed out.

7 Q. I understand. If we move to Pedersen,  
8 Pedersen is a complete subset of Jimenez-Solem, except  
9 one year, '96 to '97, correct?

10 A. That is correct.

11 Q. Okay. So let's take a look at the Cornum  
12 '91 to '96 non-overlapping date, okay, Doctor?

13 A. Not overlapping with Pedersen or with  
14 Jimenez-Solem or?

15 Q. It doesn't look like it overlaps anything,  
16 right?

17 A. I'm not sure. I'm sorry, I just don't  
18 understand. You want to look at one piece of the  
19 Cornum data that's not in either Pedersen and Jimenez-  
20 Solem; is that correct?

21 Q. Right.

22 A. Okay.

23 Q. This right here, this green part --

24 A. Okay.

25 Q. -- that we --

1 A. Okay.

2 Q. Sure. Okay. Now, Cornum looked at four  
3 counties in Denmark, correct?

4 A. Yes, that's my memory.

5 Q. Sir, did they look at all four counties for  
6 all years of their study?

7 A. I'd have to go back and look at the paper to  
8 have that level of detail. I remember it was not the  
9 entire country.

10 Q. All right. Well, let's go to Cornum page  
11 30, sir, and see what counties they studied for the  
12 years '91 to '96.

13 A. Yes, they studied some different counties  
14 depending on the year. They covered North Jutland  
15 County from 1991 to 2007. They covered Aarhus from  
16 1996 to 2007, and then they covered Ringkjober and  
17 Viborg Counties from 1998 to 2007. So there's overlap  
18 in the years there, but not all those counties were  
19 covered for the entire 1991 to 2007 period.

20 Q. All right. Let me take you back, Doctor, to  
21 the little area we were talking about, '91 to '96,  
22 sir. The only county they studied in that time frame  
23 is North Jutland, correct?

24 A. If -- yes, in that -- if, in that particular  
25 left-hand part of the green there, that is -- sorry, I

1 lost your train of thought there. Are you saying  
2 North Jutland County was the only county in 1991 to  
3 1996?

4 Q. Yes.

5 A. Yes. Then I agree.

6 Q. Okay. And they added the other counties  
7 that finally made up the four after 1996, correct?

8 A. That is correct. And the non-overlap with  
9 Pedersen to the right involved more counties than the  
10 overlap --

11 Q. Okay.

12 A. -- non-overlap to the left.

13 Q. So this number on the left, by the way,  
14 represents the total number of women in the entire  
15 study, right?

16 A. That is correct.

17 Q. And we know that number is not right for  
18 this one county for five years, correct?

19 A. No, of course not.

20 Q. Okay. This is the whole bar, so --

21 A. Correct.

22 Q. -- you know, it's one county, it's a small  
23 percentage of that, right?

24 A. Correct.

25 Q. Okay. And we know that in the entire Cornum

1 study, there were 352 patients who took Zoloft,  
2 correct?

3 A. In the entire study?

4 Q. Yes.

5 A. Again, I don't have those numbers in my  
6 memory, but I can take your word for it.

7 Q. Well, we can go to -- or we can go to page  
8 33, table 2, Doctor.

9 A. Fine.

10 Q. 352 patients using Zoloft --

11 A. Sorry, could you go a little slower when  
12 you're checking?

13 Q. Absolutely.

14 A. Thank you. Or put it up on the screen,  
15 that's even better.

16 Q. Sure.

17 A. Except --

18 Q. Table --

19 A. -- it needs to be focused.

20 Q. -- 2, page 33.

21 A. Can you focus it?

22 THE COURT: It's too small.

23 MS. YATES: Yeah, he's searching for  
24 the pull out I think.

25 THE WITNESS: There we go.

1 THE COURT: Is that better?

2 THE WITNESS: That's better, much  
3 better, thank you.

4 BY MS. YATES:

5 Q. Okay. Right, Doctor, the study, length of  
6 study 352 sertraline which is Zoloft users, right?

7 A. Correct.

8 Q. And that's four counties over 17 years that  
9 got that total.

10 A. Correct.

11 Q. Sir, do you know the birth rate in North  
12 Jutland for the years 1991 to 1996?

13 A. I certainly don't know that from my memory,  
14 no.

15 Q. Do you know the population of North Jutland  
16 1991 to 1996?

17 A. Not precisely, no, not off the top of my  
18 head.

19 Q. All right. I assume it would be important  
20 for you to know when Zoloft was approved for use in  
21 Denmark, sir. That way you can figure out if women in  
22 Cornum actually got Zoloft, right?

23 A. Well, I -- the table you just put up  
24 described the number of individuals in the Cornum  
25 study who took Zoloft.

1 Q. Slightly different question, Doctor.

2 A. Uh-huh.

3 Q. I assume it would be important for you to  
4 know what year Zoloft was approved for use in Denmark,  
5 so that you can actually figure out the timeframe that  
6 women could have been exposed to it, true?

7 A. No. I was just referring back to the  
8 original author's Cornum and their description over  
9 those time periods over the number of pregnancies, for  
10 which they had out -- birth defect outcomes and their  
11 subcategories of how many of those women were exposed  
12 to Zoloft.

13 Q. Right, Doctor, but I'm talking about non-  
14 overlapping data right now, so let's stay focused. '9  
15 to '96, we already know it's one county not four,  
16 right?

17 A. Yes. But if you're going to talk about non-  
18 overlapping data, you have to put in the right-hand  
19 side where you're comparing Cornum and Pedersen.

20 Q. Sir, I promise you I'm going to cover this  
21 entire chart, stick with me.

22 A. Okay.

23 Q. I have to break it down into sections, okay.

24 A. Okay. I'm just going to point out that when  
25 it takes us off track.

1 Q. '91 to '96 were one county.

2 A. Correct.

3 Q. Right. Now, wouldn't it be important for  
4 you to know what year Zoloft was approved in Denmark  
5 to find out when women could've been first exposed to  
6 Zoloft?

7 A. Not with regard to the overlap, no.

8 Q. Okay. Let's take out the overlap then.  
9 Wouldn't you like to know when Zoloft was approved, so  
10 that you can determine whether the women exposed in a  
11 certain timeframe could've taken Zoloft?

12 A. I took the data as reported by the authors  
13 of the study that when they said a woman took Zoloft,  
14 I had to take that at face value. I could not  
15 undercut their reporting of the data.

16 Q. All right. Let's try a different approach.  
17 You're familiar with a document called the PSUR?

18 A. Periodic Safety Update Report, yes.

19 Q. Right. You refer to it in the appendix of  
20 your report?

21 A. Yes, I probably do.

22 Q. Okay. Well, let's go to page 523 of that  
23 document that you refer to in the appendix of your  
24 report, and let's just look when Zoloft was approved -  
25 - sorry, and when Zoloft was approved in Denmark.

1 Approval 2nd of July 1993, correct?

2 A. You need to focus it just a little better  
3 for my eyes.

4 Q. Not even the pull-out?

5 A. Not even the pull-out, it's blurry. Maybe  
6 it's just me.

7 Q. I think you said you wanted it to be blurry  
8 yesterday. Was that your --

9 A. When I'm reading words, I actually don't  
10 like them blurry. Okay. So that's the date of  
11 approval you're telling me there, so --

12 Q. Right.

13 A. -- date of approval of Zoloft in --

14 Q. Denmark.

15 A. Okay.

16 Q. Okay. So if that's the date of approval,  
17 Doctor, women before that date could not have been  
18 exposed to Zoloft, correct?

19 A. I assume that is correct, yes.

20 Q. All right. Now, you're familiar with after  
21 approval, there's also usually a launch date when the  
22 medicine goes on the market, correct?

23 A. Correct.

24 Q. Okay. Do you know the launch date in  
25 Denmark for Zoloft?



1 A. No.

2 Q. Okay. Let's look. Launch date in Denmark  
3 January 17, 1994. Do you see that?

4 A. I do.

5 Q. Okay. So in the Cornum population, the non-  
6 overlapping one county, we know that prior to January  
7 1994, none of those women could have been exposed to  
8 Zoloft, right?

9 A. That is the assumption, yes.

10 Q. Okay. So no -- okay. And then we do know  
11 that for one county, for that one year, some of the  
12 352 from the entire study could have received Zoloft,  
13 right?

14 A. That is the assumption, yes.

15 Q. Okay. Let's move to the Pedersen data, and  
16 this '96 to '97, there's no overlap, right?

17 A. I'm sorry, I'm lost with you now. You said  
18 there's no overlap between '96 and '97?

19 Q. In the Pedersen data --

20 A. Oh, with Jimenez-Solem, we've switched now,  
21 is that --

22 Q. '96 to '97, no overlap with Jimenez-Solem,  
23 right?

24 A. Okay. So you just have to be precise,  
25 because we were talking about Cornum and Pedersen up

1 to now, and now we've flipped to Pedersen to Jimenez-  
2 Solem.

3 Q. All right. Stick with me, Doctor.

4 A. Okay.

5 Q. The reason I'm referring here to Pedersen  
6 and Jimenez is they use the entire country's registry,  
7 right?

8 A. Correct.

9 Q. So there is some overlap Cornum and  
10 Pedersen, but only four counties, let's set that to  
11 one side, okay?

12 A. Okay.

13 Q. We know that these two, Jimenez-  
14 Solem/Pedersen looking at the same registry, no  
15 overlap, one year. With me?

16 A. No overlap on the left for one year, and no  
17 overlap on the right for several other years.

18 Q. Got it. Let's stick on the left for now,  
19 Doctor, okay?

20 A. Uh-huh.

21 Q. All right. And in Pedersen, for the study  
22 years '96 to 2003, so the entire study there were 527  
23 women who filled two or more prescriptions. Do you  
24 remember that?

25 A. I don't remember off the top of my head, the

1 actual raw numbers from the papers.

2 Q. Would you like to confirm?

3 A. It's -- I'm completely within your hands,  
4 whatever you would prefer.

5 Q. Okay. Well, if ever you want to check  
6 anything, you just let me know because that's table 3,  
7 page 2, okay?

8 A. Of Pedersen?

9 Q. Of Pedersen.

10 A. Okay.

11 Q. Okay. All right. And then it's a lower  
12 number for one prescription, 259, but two or more 527,  
13 one prescription 259, right?

14 A. Okay.

15 Q. Okay. And that total number of exposed  
16 women is for eight years, correct?

17 A. I believe so, yes.

18 Q. All right. Now, from '97 all the way up to  
19 2009, certainly those years with Pedersen and those  
20 years with Cornum are subsets of Jimenez-Solem,  
21 correct?

22 A. That is the understanding, yes.

23 Q. Now, another study came out, also looking at  
24 Denmark, it looked at beyond Denmark, Finland, Iceland  
25 and Norway and Sweden, right, and that's Furu.

1 A. That is correct.

2 Q. And that came out in 2015?

3 A. Yes.

4 Q. Studied about 2.3 million women.

5 A. Correct.

6 Q. And the years that Furu studied are 1996 to  
7 2010, correct?

8 A. That is my memory, but again I'm relying on  
9 memory now.

10 Q. Okay. So Furu starts '96 and if we go up to  
11 -- if we use your scale for Furu, the total number of  
12 women in that study goes way off your chart, right,  
13 2.3 million?

14 A. It's much -- well, it's -- yeah, it's about  
15 50 percent higher.

16 Q. Fifty percent, this is a hundred and --  
17 well, 1.4 million, right?

18 A. And 2.3 is a little more than 50 percent  
19 higher, yeah.

20 Q. We've got to get a little bit up there,  
21 right?

22 A. Yeah.

23 Q. 2.3. And we know it goes to what, 2010. I  
24 did not go to art school. So that's Furu, right?

25 A. Except it's not just Denmark as you pointed

1 out, it's --

2 Q. It's bigger.

3 A. It's not only bigger as you've indicated,  
4 it's different countries.

5 Q. Okay. And they look to the Danish registry  
6 as well as others, so Jimenez-Solem and Pedersen are  
7 complete subsets of Furu on the Danish data, correct?

8 A. Correct.

9 Q. Okay. And then Cornum, what do we have,  
10 also a complete subset with the exception of this --

11 A. Correct.

12 Q. -- two years that people could have got  
13 Zoloft in --

14 A. Correct.

15 Q. -- one county.

16 Now, in your report, Doctor, you say --  
17 strike that.

18 Let's stick with Furu for a minute. Furu,  
19 this big 2.3 million women, found no statistically  
20 significant association between Zoloft for several  
21 cardiac findings, correct?

22 A. That is my memory. Again, I can't read off  
23 the numbers from the top of my head.

24 Q. All right. Well, let's go through them. I  
25 think it's page 7. Or page 5, Figure 2, sorry. Okay.

1 MS. YATES: Yeah, you're definitely  
2 going to have to enlarge that.

3 Q. So Furu found no statistically significant  
4 association between Zolofit and any cardiac defect,  
5 correct?

6 A. Again, it's too blurry for me to read.

7 Q. Yeah, we --

8 A. Can you point me to the --

9 Q. We're going to pull it out, Doctor.

10 A. Okay.

11 Q. Also, you have a hard copy in front of you  
12 if that's --

13 A. That's what I was trying to go to, but it's  
14 a little hard to listen and look things up at the same  
15 time. Where is it in the binder you just gave me?

16 Q. It should be in alphabetical order under F  
17 for Furu.

18 THE COURT: And you said page 5?

19 MS. YATES: Page 5, Your Honor, table -  
20 - at Figure 2.

21 THE WITNESS: Okay. Now, I've got the  
22 hard copy in front of me. It's much easier for me to  
23 --

24 BY MS. YATES:

25 Q. All right. No statistically significant

1 finding for any cardiac defect, correct?

2 A. You're talking about for sertraline?

3 Q. Yes.

4 A. Yes. It's -- yes, the odds ratio, just to  
5 make sure we're looking at the same thing, I'm reading  
6 an odds ratio of 1.28. You want the adjusted odds  
7 ratio, I assume.

8 Q. Oh, I think we want the adjusted, don't we,  
9 Doctor?

10 A. Yeah, well, I just want -- I just need to  
11 know exactly where you're talking about, because there  
12 are a lot of numbers on this table.

13 So you're talking about the 1.13, 13 percent  
14 increase in risk associated with Zoloft with a  
15 confidence symbol going from .93 to 1.38. Are we  
16 talking about the same number?

17 Q. Yes. That would be not statistically  
18 significant, Doctor, right?

19 A. At the 5 percent level, that is correct.

20 Q. Okay. An atrial -- Furu found non-  
21 statistically significant finding, atrial and  
22 ventricular septal defects, correct?

23 A. For atrial and ventricular septal for  
24 sertraline, yeah, the odds ratio was a 5 percent  
25 increase in risk, but with a confidence interval going

1 from .82 to 1.35, yeah, that's on the screen.

2 Q. 1.05, right?

3 A. 1.35.

4 Q. 1. -- no, I meant the odds ratio.

5 A. Oh, the odds ratio is 1.05, yes, correct.

6 Q. Okay. Dr. Furu found no statistically  
7 significant association between conotruncal and major  
8 arch anomalies, correct? Odds ratio 1.02, confidence  
9 intervals .48 to 2.15.

10 A. Correct.

11 Q. Furu found no statistically significant  
12 finding for an atrial ventricular septal defects,  
13 correct?

14 A. Yes, there we have a much bigger odds ratio,  
15 but much wider confidential interval, correct. That's  
16 what's correct is what's on the screen.

17 Q. And same question, non-statistically  
18 significant finding for right ventricular outflow  
19 tract obstructions, correct?

20 A. Yes. Again, 40 percent increase in risk,  
21 but the confidence interval as described there.

22 Q. And Furu found a non-statistically  
23 significant finding for left ventricular outflow tract  
24 obstructions, correct? Oh, did I just do that one, I  
25 apologize. Did I do right and left?



1 A. No, you did right and left.

2 Q. Okay. Sorry.

3 A. That's okay.

4 Q. So, Doctor, while we're talking --

5 MS. YATES: You can take that down.

6 Q. While we're talking results and conclusions,  
7 let's turn to Jimenez-Solem for a minute. Jimenez-  
8 Solem concluded that the significant odds ratio that  
9 they reported were not the results of ingestion of  
10 Zoloft, correct?

11 A. Yes. They believed it was due to a sort of  
12 unknown confinder associated with filling  
13 prescriptions, which I think is a little -- we could  
14 talk about that in detail, we didn't --

15 Q. You disagree with that peer review published  
16 opinion.

17 A. I disagree with that interpretation of the  
18 results, yes, as I described yesterday. I think they  
19 made the comparison both indirectly instead of  
20 directly comparing the pause to the non-pause, which I  
21 think gets more directly at the confounding by  
22 indication phenomenon.

23 Q. You disagree with the authors?

24 A. I disagree with the authors on that  
25 interpretation, yes.

1 Q. Right. Doctor, let's move to Louik. A lot  
2 was talked about Louik, corrections. Mr. Zonies, I  
3 thought I interpreted as saying, let's just take it  
4 out. I say let's leave it in, what do you think?

5 A. I don't understand what you mean by either  
6 what he meant by take it out or leave it in.

7 Q. I think he said there's so many mistakes in  
8 it, just to push it to one side.

9 A. No, I don't -- I didn't get that from what  
10 he said. I certainly don't believe it should be  
11 entirely ignored just because of that transcription  
12 error.

13 Q. Okay. So then let's look. You did a --  
14 well, we saw a few forest plots yesterday, now the  
15 Court has the benefit of -- and you were kind enough  
16 to provide us one, but a large sheet with all those  
17 old cardiac findings. That was the forest plot that  
18 you went to yesterday; is that right?

19 A. Yeah, I would call it a visualization rather  
20 than a forest plot, but I don't mind if you -- I  
21 understand.

22 Q. Visualization.

23 A. Yeah.

24 Q. Now, I may have misheard yesterday. I  
25 thought you said that you were not using it for

1 consistency, but isn't that only what you're using it  
2 for?

3 A. I -- if I said that, that's not what I  
4 intended. I wanted it to -- I think what I said  
5 yesterday was I wanted a way to put all of the results  
6 on a single sheet of paper for ease of reference, and  
7 to see the overall span of findings, whether it's for  
8 every finding or just the -- all cardiac findings or  
9 some of the subcategory findings.

10 Q. All right. And so I'm clear, you're not  
11 using it to support your causation opinion.

12 A. I'm not using the plot itself, no, I'm using  
13 all that data that's on the plot obviously that's  
14 going into the opinion.

15 Q. All right. Now, when you did your first  
16 expert report, you had a different forest plot; is  
17 that right?

18 A. I think I had an expert report for a state  
19 case, the very first one I wrote that I had a  
20 different visualization, that is correct.

21 Q. Right.

22 A. I just didn't have it on the log scale, and  
23 then I -- we discussed that at deposition, and I  
24 agreed that it was better to change it to the log  
25 scale.

1 Q. So let's look at that first forest plot. It  
2 was from the Robinson case, which was the case that  
3 was tried in the PCCP.

4 A. I don't remember which case it was actually,  
5 I just know it was a state case.

6 Q. You testified in that case, right?

7 A. I did, but I've been deposed I think two or  
8 three times. I lose track of the cases, it makes no  
9 difference to me.

10 Q. No, but I mean, you were sitting in a  
11 witness chair in front of a jury in that case. Do you  
12 remember that?

13 A. You know, I can't even remember the name of  
14 the plaintiff, individual plaintiff.

15 Q. Okay, fine. All right. So this is your  
16 first forest plot that was in your state court case  
17 report. Does that look familiar?

18 A. Yes. I still can't see it because it's  
19 blurry. It's more blurry than it was yesterday, I  
20 don't know why, but I take your word for it. It looks  
21 familiar.

22 Q. It looks familiar. And as you said, that  
23 was on a linear scale, right?

24 A. That was on a linear scale, the  
25 visualization, yes.

1 Q. And, Doctor, it was pointed out to you that  
2 a linear scale can distort things even further to the  
3 right, right?

4 A. Well, the point was made when we discussed  
5 this at deposition that the area of protection, that's  
6 the area on the X axis from 0 to 1 is compressed,  
7 because of the asymmetry. And so I agreed with that  
8 and was perfectly happy, in fact, a Pfizer lawyer  
9 produced the equivalent to this on the log scale, and  
10 I was perfectly happy to discuss that one. And now I  
11 have got around that, put all of these on the log  
12 scale.

13 Q. Right. Because the linear scale distorts  
14 it, doesn't it?

15 A. Well, it makes it harder for the eye,  
16 because if you're going to try and use this in the way  
17 I was describing yesterday, with the eye, it's  
18 asymmetric between 0 and 1 and 1 to 10, and in this  
19 case 1 to 7.

20 Q. All right. And then actually, you removed  
21 the forest plot altogether from your MDL report,  
22 right?

23 A. I think I probably took it out, yes, but I  
24 used it as an exhibit I believe in the trial on the  
25 log scale.

1 Q. Right, okay. Now, let me talk about Louik  
2 and the correction. Doctor, the correction in Louik  
3 had a statistically significant finding of 1.2  
4 corrected to a non-statistically finding, non-  
5 statistically significant finding of 1.0, correct?

6 A. No, that's not correct.

7 Q. That's not correct?

8 A. No.

9 Q. Confidence interval.

10 A. I know the words, do you want to restate  
11 your question?

12 Q. Sure. It's going to be a long day, Doctor,  
13 because I am not a mathematician.

14 The confidence, the change and correction  
15 that was made in Louik, I apologize, the lower  
16 confidence interval went from a 1.2 to a 1.0.

17 A. Yes, the odds ratio stayed the same, and it  
18 was the lower bound of the confidence, and the upper  
19 bound stayed the same, but the lower bound was changed  
20 from 1.2 to 1.0.

21 Q. Right. And the New England Journal of  
22 Medicine when they were corresponding with the authors  
23 wanted them to remove all reference to significance,  
24 because that finding was no longer statistically  
25 significant.

1           A.    There certainly was discussion about  
2   changing the emphasis on that.  I don't want to say  
3   that was their exact words, but I don't think they  
4   wanted to remove all mention of it, but I think they  
5   felt bound by the fact that it now -- the confidence  
6   interval contained one to change the emphasis away  
7   from stating it as a statistically significant result,  
8   that is correct.

9           Q.    It's more than changing an emphasis, sir.  
10   It's removing a word that says statistically  
11   significant, because it's no longer statistically  
12   significant.  That's the standard the Journal uses,  
13   correct?

14          A.    Well, we certainly could look at the e-mails  
15   and look at their exact language back to Dr. Louik, I  
16   don't remember it word-for-word.  But they were caught  
17   by the fact that their description of how you should  
18   emphasize results in papers is influenced by whether  
19   the result is statistically significant formulated --  
20   formula.  And that's what -- they didn't want just to  
21   publish the change in the number.  They also wanted to  
22   change a little bit of the emphasis of how it was  
23   spoken about in the paper.

24          Q.    Right.

25          A.    And we should probably, if we're really

1 going to discuss that into detail, we should probably  
2 put the e-mail up from the New England Journal,  
3 because that gives explicitly what they were and  
4 explicitly the reaction of the authors to that, which  
5 they thought that was crazy, but they still -- the  
6 editor thought it was crazy, but they still had to do  
7 it.

8 Q. Right. Because that is --

9 A. You shouldn't take my word for it, just put  
10 the e-mails up.

11 Q. Actually, sir, why don't we go straight to  
12 the correction published by the New England Journal of  
13 Medicine. I will -- there was debate in the e-mails  
14 about .98 or 1.02 and rounding to 1, right? And that  
15 revealed that actually the 1 has been rounded up from  
16 .98, correct?

17 A. Yes. Well, that would be standard in that  
18 case.

19 Q. Right, that's standard. As is the New  
20 England Journal of Medicine saying remove the word  
21 significance when it's no longer statistically  
22 significant, correct?

23 A. I think that is the standard of the New  
24 England Journal, yes.

25 Q. And that's what the correction -- set aside



1 the e-mails, we saw them, the correction removes the  
2 word significance because it was no longer  
3 statistically significant, correct?

4 A. In the judgment of the Journal that is  
5 correct, yes.

6 Q. Not in the judgment of the Journal, sir,  
7 using the standard they use.

8 A. If you read the e-mails from every  
9 statistician involved in that debate, including the  
10 authors of the papers, they believe that distinction  
11 to be meaningless. The Journal has a formal standard  
12 and I -- that's what they use, for better, for worse,  
13 that's what they use.

14 Everyone else in that debate agreed that it  
15 was a meaningless distinction. I don't have any  
16 debate. The results is not statistically significant.  
17 My opinion does not hang on it being statistically  
18 significant.

19 The confidence interval goes from 1.0 to 3.  
20 something, 3.8 or whatever it was, the upper band.  
21 The entire set of values of the odds ratio that are  
22 compatible with the data, in an interpretation of the  
23 confidence also has the risk is raised.

24 Statisticians do not hinge opinions,  
25 therefore, in a case where there are multiple pieces

1 of data on that single statistical significance. I  
2 thought we discussed that effectively yesterday.

3 Q. Do you remember my question?

4 A. Well, you can certainly ask it again, that's  
5 fine.

6 Q. I'm just asking if you remember it, Doctor.

7 A. You asked me about whether the Journal said  
8 it was statistically significant or not, and I said,  
9 no, they said it wasn't statistically significant  
10 anymore.

11 Q. And I think you also said that it really  
12 doesn't make much difference, if any, to your opinion  
13 because you don't rely on statistical significance.

14 A. No, that's not what I said. Let me say what  
15 I did say, which is in a single study, the issue of  
16 statistical significance plays a much greater role  
17 because it's the only information we have at that  
18 point. And the role of chance has to be addressed.

19 When you're looking at the Louik paper now  
20 in the big picture in that entire list of studies,  
21 that's not the sole source of statistical  
22 significance, nor the sole source of information about  
23 that particular subcategory. And it's important to  
24 remember here, we've moved to talking not about all  
25 cardiac, but to a subcategory where results are more

1 variable.

2 So in that bigger context, the change of a  
3 confidence interval lower bound from 1.2 to 1 is  
4 important to correct. It did change my viewing of the  
5 data, it had to because it changed, but it did not in  
6 the end affect my overall opinions.

7 Q. Okay. I think you said yesterday it had a  
8 very slight impact on your opinion.

9 A. Yes, because as I pointed out yesterday if  
10 you look at all of the data on one piece of paper, and  
11 then you change -- before the change and after the  
12 change, it's almost undetectable to the human eye the  
13 impact that change makes.

14 Q. And the subcategory that changed was all  
15 septal, right?

16 A. That is correct.

17 Q. And as you've told us several times, your  
18 focus was all cardiac.

19 A. That is correct.

20 Q. Now, I just want to address something else.  
21 There was another correction that the authors are  
22 either submitting or proposing to submit, but that has  
23 nothing to do with the results, the risk estimates or  
24 the confidence intervals, correct?

25 A. No, that is incorrect.

1 Q. Okay. Let's put up the e-mail then to Mr.  
2 Zonies of August 31.

3 MS. YATES: Do we have that?

4 (Pause)

5 MS. YATES: No, that's not it, so I can  
6 find it in the slides? Sorry.

7 (Pause)

8 MS. YATES: It's the one that says New  
9 England Journal of Medicine correction again. Okay.

10 Q. This is the e-mail. Doctor, can you read  
11 that? Is that clear enough for you?

12 A. Yes, I can read that one fine, thank you.

13 Q. All right. So this is the -- this is from  
14 Mr. Zonies' slide, this is the most recent correction.  
15 And the authors in this e-mail state clearly, "We wish  
16 to state clearly, the risk estimates in confidence  
17 intervals in the LGA which we provided on July 27,  
18 2015 in response to subpoena are correct." Did I read  
19 that correctly?

20 A. You read that correctly, yes.

21 Q. All right. So -- and what they're  
22 correcting is something about some of the descriptions  
23 that talked about the variables, correct?

24 A. They're describing which variables were used  
25 in the adjustments for confounding that produced the

1 confidence in all they reported in the New England  
2 Journal.

3 Q. Right. So that's a descriptive error, but  
4 they're standing by their results, even though all  
5 those variables were not specified in the article,  
6 correct?

7 A. They're standing by the results they  
8 provided for -- from a re-analysis of the data in  
9 July, which we readjusted the data for a slightly  
10 different set of confounders than from the set they  
11 described in the original journal article. That was  
12 the error I detected when I saw the logistic  
13 regression.

14 This is slightly different. Now, it's not a  
15 big deal to me. We pointed out because we wanted to  
16 get the right results with all this fuss about the  
17 confidence interval.

18 Had they adjusted for exactly the variables  
19 they said they did in the article, the confidence  
20 interval would change. That's why I'm saying, okay,  
21 now they've said, ah, well, actually what we did in  
22 July of this year was what we are saying we actually  
23 did five years ago, and now we want to go back and  
24 change the article from five years ago, and said  
25 actually we didn't quite adjust for those variables

1 the way we described them five years ago. We want to  
2 change that. That's what that e-mail describes.

3 It doesn't matter to me. What it does point  
4 out is that if one changed back to the variables that  
5 they said they adjusted for, that confidence bound,  
6 lower bound could easily be above 1 now. So it's a  
7 moving target, it's not a very important moving target  
8 for the reasons we've discussed at length.

9 But this whole fixation about 1 is  
10 illustrated again by the fact that if you, in fact,  
11 use slightly different sets of variables that lower  
12 confidence bound is going to change, not much, but it  
13 could go from 1.0 to .99.

14 Q. Doctor, that is rank speculation on your  
15 part.

16 A. No, it's not speculation. It could easily  
17 go from 1 to 1.01, I agree, we don't know, and if you  
18 take out -- in and out variables, those lower bounds  
19 will change. That is not speculation, that is  
20 absolute hard statistical fact, it will not stay the  
21 same --

22 Q. Well --

23 A. -- if you change the variables.

24 Q. Let's see if we can breakdown this e-mail  
25 because what they're saying is in the process of

1 reviewing the original regression analysis, which we  
2 retrieved in response to the subpoena dated July 15th,  
3 2015, and which was provided on July 27th, we  
4 discovered some inconsistencies between what was  
5 included in that analysis and what appeared in the New  
6 England Journal of Medicine report, right?

7 A. That's what they said. Yes, actually I  
8 discovered the inconsistency and pointed it out, but  
9 this is what they are sending back to the Journal now.

10 Q. I got it. They're saying, here's our data  
11 based on variables, here's our results based on those  
12 variables, but the variables that are actually stated  
13 in the New England Journal of Medicine there's a few  
14 missing.

15 A. Yes, that is correct, and the way they  
16 described one other set of variables was not correct  
17 in the paper, that's described later on about the  
18 variable where they described the history of a birth  
19 defect in a first degree relative that was wrong,  
20 taking their word for it. That should've read history  
21 of a cardiac defect in a first degree relative, so  
22 that's a little different. I assume they mean cardiac  
23 birth defect.

24 And the way they described the adjustment  
25 for the year of lost menstrual period was sloppy in

1 the New England Journal, and they regretted that they  
2 didn't get that more accurately described, you know,  
3 but basically, they didn't get the description of the  
4 variables in the article to correspond to the  
5 description of the variables in the analysis they  
6 provided to the Court.

7 Q. Right. But the -- so they're going to now  
8 make sure the description does match. We don't even  
9 know if the New England Journal of Medicine is going  
10 to correct it, do we?

11 A. I have no idea, no. This is fairly recent,  
12 so I don't know. And by the way, this is completely  
13 insufficient, because in principle, does that mean  
14 that all the numbers in that table, forget sertraline  
15 and septal, all the other SSRIs, do they also need to  
16 have those adjustment variables changed. Were all the  
17 analysis done with this new set of variables that they  
18 produced in July or not, I don't know.

19 Q. Doctor --

20 A. Only they know.

21 Q. -- I'm not sure if we're just not connecting  
22 or you're misinterpreting, but they get -- they do the  
23 data analysis based on a set of variables, right? And  
24 they have those results, and they stand by those  
25 results.



1 A. This is the analysis done in July, yes.

2 Q. Correct?

3 A. Correct.

4 Q. Now, they go to their paper and it doesn't -  
5 - some of the variables are missing in the  
6 description.

7 A. Correct and misstated also.

8 Q. And so they stand by their risk estimates  
9 and confidence intervals.

10 A. They -- what they say --

11 Q. They say that.

12 A. What they say here is in the confidence  
13 intervals provided in July are the variables they wish  
14 to now adjust for, and they don't correspond with the  
15 variables, they said they adjusted for back then. I  
16 think what -- to the best spin on it, they're saying  
17 that's what we meant to say five years ago in the  
18 paper. These were the variables we intended to adjust  
19 for, we got it wrong in our description of the table,  
20 we made a transcription error. We also got the  
21 description of the confounding variables incorrect,  
22 and now we have to change that. That's the most  
23 positive spin I can put on it.

24 And I assume that in fact, that change in  
25 the list of confounding variables applies to every

1 number in that table, because there are a lot more  
2 numbers in that table than simply the Zoloft or the  
3 septal heart defect number.

4 Q. If they did their analysis on variables A  
5 through J, but H, A, B, and D are not reported, and  
6 now they're just going to clean up the reporting and  
7 make sure they're all in there. That does not affect  
8 the results they found, sir. It is correcting the  
9 description of what they looked at.

10 A. That is the most positive spin, but it makes  
11 the point that had they produced an analysis in July,  
12 that corresponded to what they claimed they were  
13 adjusting for in -- five years ago in the New England  
14 Journal, that lower confidence bound will change a  
15 little, not importantly.

16 But that's why in a sense, this is all a  
17 tempest in a tea cup. Because if you put in or leave  
18 out one of these variables, that confidence interval  
19 bound may well slip below 1. The confidence interval  
20 for the original reporting of this data differed from  
21 what they produced in the New England Journal.

22 Confidence interval bounds change a little  
23 bit, not just because the data is changing, but as you  
24 put in a confounding variable or not, even if that  
25 confounding variable is irrelevant, it will change

1       them a little bit. And that's why statisticians don't  
2       put a tremendous amount of emphasis on the upper and  
3       lower bounds of a confidence interval. It's misplaced  
4       emphasis.

5               And, in fact, to be frank, this whole  
6       discussion is a misplaced emphasis on not where the  
7       truth is, but on the periphery. It's not important,  
8       but it does make a point that which variables you put  
9       in, will change the confidence interval, and it may  
10      make it a little bigger, it may make it a little  
11      smaller. That's why the exact value isn't that  
12      crucial.

13             And none of these, by the way, are changing  
14      the actual estimate of the increased risk, which has  
15      remained at 2 pretty much throughout their reporting  
16      of their data.

17            Q.    Do you remember my question?

18            A.    I think I answered the question.

19            Q.    No, do you remember my question, sir?

20            A.    Well, we can go back and you can read it to  
21      me again.

22            Q.    No, I'm trying -- we have an amount of time,  
23      and I'm --

24            A.    I'm happy to stay here as long as you want.

25            Q.    Well --

1           A.    And if it helps you to reread the question,  
2   it sure helps me, so please do.

3           Q.    If the examination -- the analysis was done  
4   on a data set A through K and they have the results,  
5   and we have those results, but what is actually in the  
6   article is missing B, C and D, and now they're going  
7   to correct the description.

8                   Correcting the description does not change  
9   the results of their analysis, yes or no?

10          A.    No, it doesn't change the results. The  
11   results correspond to a specific set of confounding  
12   variables. What does change is if you change the  
13   choice of the confounding variables. And the choice  
14   of the confounding variables is different in the paper  
15   than in the analysis they ran for the Court. That's  
16   the only point this e-mail is dealing with.

17          Q.    I must -- I'm going to move on, I must not  
18   be communicating.

19                   Let's go to your forest plot that was used I  
20   believe in the Robinson trial and the one that you  
21   used obviously has been in here has been updated,  
22   right? There are more studies, right?

23          A.    There is some new studies, yes.

24                   MS. YATES: And I may need to pull this  
25   a little closer, Your Honor, I apologize.

1 THE COURT: yes.

2 MS. YATES: May I just --

3 THE COURT: You may hold it there, if  
4 you can pick up everyone's voice.

5 BY MS. YATES:

6 Q. So on this one, appropriately so, we have  
7 Louik at that time, because it was showing a  
8 statistically significant result, right?

9 A. Correct. It was -- the 1.2 is what's  
10 changed.

11 Q. Right. And now it's gone down into the  
12 black zone.

13 A. I moved it down because it's not significant  
14 anymore --

15 Q. Right.

16 A. -- according to the New England Journal.  
17 And I've of course moved the 1.2 to 1 so it just clips  
18 the line at 1, as we saw yesterday.

19 Q. Okay. Now, this is a log scale, right?

20 A. Correct.

21 Q. And when you do a log scale, the odds ratio  
22 is right in the middle of the confidence intervals,  
23 correct?

24 A. Correct.

25 Q. And if we look at Louik, it's not, is it?

1           A.    That's very slightly off center, and that's  
2   I think what Dr. Kimmel noted and that's what led to  
3   that discovery.

4           Q.    Right. But you didn't notice that out of  
5   all of these studies, there was something wrong with  
6   the Louik data, based on your own forest plot.

7           A.    No, I confess, my eyes are not that good, I  
8   did not see that asymmetry, no, in that one particular  
9   confidence interval. It's not very asymmetric, but it  
10   is a little bit.

11          Q.    It sort of jumps out, doesn't it, Doctor?

12          A.    Well, I guess it didn't to me. It may have  
13   to you. And it's corrected now, so I --

14          Q.    Okay. The good news when I turn pages means  
15   that we've covered it. All right. At the time of  
16   this earlier forest plot, sir, Louik was the only  
17   statistically significant finding on septal defects  
18   that was -- that replicated something from the Denmark  
19   studies, correct?

20          A.    Yes. If you lump all three, there were the  
21   Danish studies which have some form of replication as  
22   I discussed yesterday and we discussed earlier, but if  
23   you put those altogether, then the only other study of  
24   the ten or so that were in there at that point was the  
25   Louik one with regard to all septal.

1 Q. Okay. Well, we didn't talk about  
2 replication, Doctor, we talked about overlap, right,  
3 two different concepts.

4 A. Well, the whole point of the overlap is the  
5 idea of replication and whether we're getting any new  
6 information from separate studies of this overlapping  
7 populations.

8 Q. All right. Doctor, let's change subjects.  
9 Let's go to Berard 2015 paper, okay.

10 A. Sure.

11 Q. You recall testifying in February 2015 Frye  
12 hearing before Judge Bernstein?

13 A. I do remember the experience, yes.

14 Q. You were asked about Dr. Berard's study.

15 A. I was by the Pfizer lawyer, yes.

16 Q. And you were asked whether you could check  
17 Dr. Berard's calculation from her paper, right?

18 A. Correct.

19 Q. You were asked if you could calculate the  
20 odds ratio.

21 A. I was.

22 Q. And you testified you could do that.

23 A. I did.

24 Q. And, in fact, during the break in a hearing,  
25 you calculated the crude (indiscernible) ratio to be

1 1.3, correct?

2 A. Well, I don't remember the actual number.  
3 It depends on -- I think there were several in her  
4 paper, but I did one that they were asking me to do at  
5 the hearing during a break, and I confirmed her  
6 calculation.

7 Q. No, well, let me show you your testimony.  
8 You don't remember that it was 1.35?

9 A. No, I don't remember the numbers.

10 Q. All right.

11 MS. YATES: Let's bring up the  
12 transcript.

13 THE COURT: Do I really care what Dr.  
14 Berard says and whether he can calculate her numbers?

15 MS. YATES: Well, if there's a mistake  
16 in her paper and it's the only other statistically  
17 significant finding, Your Honor, I don't know.

18 THE COURT: Unless he depends on it.

19 BY MS. YATES:

20 Q. Doctor, let me --

21 MS. YATES: You know what, Your Honor,  
22 let me cut to the chase.

23 Q. We've seen that there are two findings  
24 within Dr. Berard's paper that are statistically  
25 significant, but that there is certainly debate as to



1       whether there are mistakes in those two numbers,  
2       right?

3           A.     There was a debate in those two numbers, and  
4       those are the two that changed the most from the crude  
5       calculations that were done based on raw data from the  
6       paper that Dr. Kimmel most specifically did the whole  
7       set.

8           As I discussed at some length yesterday, the  
9       dispute is about the confidence intervals, and  
10      therefore the level of statistical significance. Dr.  
11      Berard claims in her paper to have used a more  
12      sophisticated statistical methodology for calculating  
13      the confidence intervals that she's forced to do  
14      because of the multiple pregnancies for women that --  
15      that doesn't occur in almost all these other studies.  
16      There's a little bit about that in Furu by the way  
17      that we could discuss.

18           That's -- there's no debate about that as  
19      far as I'm aware. I've, as I said, told people that's  
20      the reason why there is this discrepancy between these  
21      crude calculations that everyone is doing, and what  
22      Dr. Berard and her team have reported. And she was  
23      explicit about checking the numbers, pointing this out  
24      that, in fact, she had to deal with this issue with  
25      multiple pregnancies. And I don't believe there's any

1 debate about that, as yet, that --

2 Q. All right. Are you aware --

3 MS. YATES: And, sorry, Your Honor, I  
4 do have to go into it apparently.

5 Q. Let me show you a slide that I believe was  
6 used in opening by Mr. Cheffo and this is Dr. Berard's  
7 2015 paper, I'm trying to -- so let's just look at the  
8 title. All of the Zolof findings match and are  
9 confirmed as non-significant, okay.

10 So when you go to OpenEpi, every other  
11 result in Dr. Berard's 2015 publication, you plug in  
12 her numbers on an OpenEpi and they're correct.

13 A. Well, they're not correct. They coincide  
14 with Dr. Berard's calculations using the more  
15 complicated software.

16 Q. They coincide.

17 A. Correct.

18 Q. Okay. And then we come to the two  
19 statistically significant findings in her paper and  
20 they don't coincide on OpenEpi, right?

21 A. No, the OpenEpi here, if her description of  
22 her data is correct, would be an incorrect statistical  
23 procedure to use for this data because it doesn't deal  
24 with the issue of variability correctly when there are  
25 multiple pregnancies per women.

1 Q. Doctor, are you aware that Dr. Berard did an  
2 abstract in 2013?

3 A. I think I am aware, and I think in there,  
4 she had crude results that she subsequently updated in  
5 her paper.

6 Q. And that abstract is the paper that later  
7 was published, right?

8 A. Well, it's a precursor. I mean, the --  
9 usually papers change a little bit from an abstract  
10 and it did in this case, is my memory.

11 Q. Okay. And all of her numbers in the  
12 abstract except those two findings that become  
13 statistically significant match the other paper,  
14 right?

15 A. I'd have to check. But my memory is the use  
16 of the generalized estimating equation approach  
17 probably happened between her abstract and her paper.  
18 That would be my guess.

19 Q. And that's a guess, right, Doctor, because  
20 you don't know?

21 A. Well, all I know is that Dr. Berard herself  
22 said that she had pointed out that people were  
23 misinterpreting her papers' results by applying  
24 OpenEpi calculations because they were not paying  
25 attention to the multiple pregnancy issue, and that

1 she had indeed used a more sophisticated piece of  
2 software and had rerun the analysis on request, and  
3 checked the results of the paper.

4 As I testified yesterday, beyond that I have  
5 no way of checking --

6 Q. Right.

7 A. -- if Dr. Berard is either telling the truth  
8 or if --

9 Q. If the data is accurate.

10 A. Well, let alone whether the data is  
11 accurate, whether she did the analysis correctly from  
12 raw data, I haven't got access to that data.

13 Q. All right. So you think we have the  
14 abstract and then she does this GEE modeling, right,  
15 for the paper and that's what changes the two results  
16 according to Dr. Berard.

17 A. Well, you would expect it to change --

18 Q. No, no, please, Doctor, just answer my  
19 question. That's what Dr. Berard says, right? We  
20 have the abstract, and then in the paper she uses the  
21 DEE model and that changes these two findings and they  
22 are no longer -- they no longer coincide with OpenEpi,  
23 because she used this modeling, right?

24 A. That's the speculation of the difference  
25 between the abstract and the paper, yes.

1 Q. Okay. Let's go to tab 203, please. Doctor

2 --

3 MS. YATES: Show the title, please.

4 Q. This is Dr. Berard's 2013 abstract, sir.

5 Okay.

6 A. Okay.

7 Q. She used the GEE model in her abstract,  
8 didn't she, sir?

9 A. Apparently. So my speculation of why there  
10 might be a difference between the abstract, so we are  
11 back to the beginning of saying she used the GEE  
12 models, I have to take the paper as the -- the peer  
13 review paper as the final version. I can't -- you  
14 have to ask Dr. Berard why there's a difference in the  
15 abstract, I don't know. I've done my best to  
16 speculate.

17 Q. Right. And in fact, Dr. Berard, in her  
18 abstract, came up with numbers that matched OpenEpi  
19 didn't she, using the GEE model?

20 A. I haven't checked that, but I believe that's  
21 correct, yeah.

22 Q. Okay.

23 A. That's what made me speculate that, that it  
24 looked like OpenEpi but --

25 Q. All right. So you asked for Dr. Hubrix's

1 data, have you asked for Dr. Berard's data to try and  
2 confirm what she did?

3 A. No, I asked her to confirm and she did, but  
4 I have not gotten that data myself. I would get it  
5 for the same reasons that I haven't been allowed to  
6 get Dr. Hubrix data. I'd love to have the data for  
7 all of these studies, the raw data, but that would be  
8 a two-year project to confirm the results of every  
9 single paper in the peer reviewed literature.

10 Q. Okay. My question was just did you ask for  
11 her raw data?

12 A. And as I indicated and answered, I asked for  
13 her to confirm the results, which she claims she did.  
14 Actually she claimed her statistician confirmed the  
15 results.

16 Q. All right. Let's move on a little bit,  
17 Doctor. Your qualifications are in mathematics,  
18 correct?

19 A. No.

20 Q. Don't you have a degree -- a Ph.D. in  
21 mathematics?

22 A. I do, but I don't believe that's -- Ph.D. is  
23 the sole total of my qualifications. God forbid.

24 Q. I didn't say that, but, Dr. --

25 A. Didn't you ask me that my qualifications

1       were only in mathematics?

2           Q.    I don't think I said only.

3           A.    Oh, well they're not in mathematics solely  
4       either --

5           Q.    Okay.

6           A.    -- they're -- I have some qualifications in  
7       mathematics, less and less as I age.

8           Q.    You're a self-taught statistician, right?

9           A.    I sometimes describe myself as that. That's  
10       a little unfair to people whose lectures I sat in in  
11       my post-doctoral training where I got very good  
12       mentoring.

13          Q.    So are you --

14          A.    I think that's a little bit egotistical to  
15       put it as completely self-taught.

16          Q.    I'm using your words, Doctor.

17          A.    I indicated I often describe myself that way  
18       because I didn't take -- do a graduate program in  
19       statistics.

20          Q.    Okay. And your opinions that you're  
21       offering today of Zolofit can cause or contribute to  
22       all cardiovascular birth defects, correct?

23          A.    Correct.

24          Q.    You're not a teratologist?

25          A.    No, I'm not.

1 Q. You don't know what the teratology community  
2 requires before concluding there's causation?

3 A. I've been given documents like that at  
4 deposition, but I certainly couldn't repeat them word  
5 for word, and it's not my community, that is correct.

6 Q. No medical training, not a medical doctor?

7 A. I'm not a medical doctor, no.

8 Q. Birth defects is not your area.

9 A. Well, I have no specific area, but certainly  
10 I have not worked in birth defects as my specific area  
11 of application, no.

12 Q. And outside of your work as a litigation  
13 expert on behalf of plaintiffs suing Pfizer, you have  
14 not opined that Zoloft causes congenital heart  
15 defects, correct?

16 A. No, I'm trying to do that now with a joint  
17 paper with Hubrix, but that remains to be seen if I  
18 can succeed.

19 Q. Right. Did she get back to you after her  
20 polite too busy?

21 A She said no, she did get back to me as we  
22 described yesterday, said she thought she would try  
23 and get some of her team to help, but we haven't  
24 connected since then.

25 Q. Right. You started working on the Zoloft



1 litigation before Dr. Berard actually submitted her  
2 report in the MDL, right? You were already consulting  
3 with the plaintiffs?

4 A. That I can't swear to. I don't -- I was not  
5 involved in that first MDL as far as I'm aware --

6 Q. Right.

7 A. -- so I don't know the timing of when I was  
8 contacted, vis-à-vis, that hearing.

9 Q. Okay. Can we go to tab 154 -- oh, so we're  
10 mixing apples and oranges, Doctor. I didn't say  
11 hearing --

12 A. Oh.

13 Q. -- you were already an expert for plaintiffs  
14 when those reports, including Dr. Berard's, went in in  
15 the MDL, correct?

16 A. That I don't recall, I may well have been, I  
17 just don't -- I wasn't paying attention to those dates  
18 of her reports as to when I was contacted.

19 Q. Do I need to check?

20 A. No, no, I take your word for it.

21 Q. All right.

22 A. If you have the dates there, I --

23 Q. Okay.

24 A. -- you have them.

25 Q. All right. You've not published any

1 articles regarding congenital heart defects?

2 A. No, that's not my area of -- my personal  
3 area of research.

4 Q. You've not published regarding any other  
5 types of birth defects?

6 A. No, as I indicated, that's not my personal  
7 area of research.

8 Q. You've not published regarding Zoloft or any  
9 other SSRI?

10 A. No, I publish about GEE, not about birth  
11 defects.

12 Q. Right, that model.

13 A. Correct.

14 Q. Okay.

15 A. That model.

16 Q. Popular paper though.

17 A. It is a very --

18 Q. Correct?

19 A. -- highly cited paper, yes.

20 Q. That's what I heard.

21 You don't claim to be an expert in the field  
22 of cardiovascular medicine?

23 A. No, I'm a statistician.

24 Q. And you don't claim expertise to be able to  
25 tell the Court whether or not heart defects are

1 anatomically, clinically, or developmental  
2 heterogeneous, correct?

3 A. No, that's not my -- you should talk to a  
4 cardiologist or an expert if you want to get into the  
5 fine details of those conditions.

6 Q. But what you do agree from your perspective,  
7 is that it is important to perform sub-analyses on  
8 specific heart defects, correct?

9 A. As part of my methodology as I described  
10 yesterday, you have this conundrum when facing a  
11 question of risk when you're dealing with a rare  
12 outcome, and we discussed that length yesterday, I'm  
13 happy to go over it again, which determines the level  
14 of subcategorization that seems reasonable to the  
15 experts -- not to the statisticians, but to the  
16 experts -- and yet provides enough data for the  
17 statisticians to say we can get some level of  
18 definitive estimates of risk. And that's how I use  
19 it. And then only when you find something of interest  
20 in the larger subgroup where you've got some level of  
21 statistical precision to say something does it make  
22 sense to look at the subcategories and say, yes, I  
23 believe we have a signal here with regard to the  
24 larger category. Now as a next step in the  
25 methodology let's look at the subcategories to

1 determine whether in fact systematically one  
2 subcategory does not mirror that association you  
3 already determined. That's the methodology.

4 Q. Doctor, do you agree that it is important to  
5 perform sub-analyses on specific heart defects?

6 A. Only in the sense -- that only makes sense  
7 to me if you've determined a priori that there is a  
8 signal in the larger group. Otherwise it doesn't make  
9 sense to go down one, because if you find positive  
10 findings in the subgroup they're going to be very  
11 statistically imprecise. If you don't find anything  
12 you're no further forward.

13 So my feeling is you look at the subgroup  
14 where you have some level of statistical precision and  
15 then you go and look at the subgroups.

16 Q. Okay. So you look at the subgroups to the  
17 extent the data permits it?

18 A. Yes, I think --

19 Q. All right.

20 A. -- fair description.

21 Q. Doctor, you agree that replication is a  
22 crucial part of assessing causation?

23 A. Yes.

24 Q. And you agree that consistency is also an  
25 important part of assessing causation?

1 A. It is a part, yes.

2 Q. And it's -- you agree that it's also  
3 important to assess potential biases, including  
4 confounding, especially when the evidence is coming  
5 from observational studies, correct?

6 A. Correct.

7 Q. And that's what we have with Zoloft, right?

8 A. Correct.

9 Q. Couldn't do a randomized control trial could  
10 me?

11 A. No, unfortunately -- well from a  
12 statistician it's unfortunate, from a women's  
13 perspective maybe it's fortunate. It's not ethically  
14 possible.

15 Q. Doctor, I need to shift gears a little bit  
16 to talk about meta-analyses.

17 You rejected the Miles and McDonagh peer  
18 reviewed published meta-analyses in your report on  
19 Zoloft, correct?

20 A. Well, I didn't reject them. I don't find  
21 them particularly scientifically reliable or helpful  
22 in addressing the overall question. I discuss them in  
23 the MDL report.

24 Q. You discussed and you rejected as forming  
25 part of your opinion, correct?

1           A.     That is correct. It did not influence my  
2     opinion, and I think that is fair to say

3           Q.     And in Prozac you focused your attention on  
4     the available meta-analyses, correct?

5           A.     Yes, as I discussed yesterday in the Prozac  
6     case it started for me with the fact that Eli Lilly  
7     themselves, the manufacturer, had done their own meta-  
8     analyses, which I focused on, not specifically the  
9     large one, though it's -- Prozac is discussed in the  
10    large meta-analysis. So the manufacturer there had  
11    already done as part of their protocols a full meta-  
12    analysis of the question of whether Prozac raises the  
13    risk of certain kinds of birth defects.

14          Q.     So that was a yes?

15          A.     Yes, and that's not available to me here,  
16    because as far as I'm aware Pfizer has not done a  
17    meta-analysis, they did not consider that to be part  
18    of their methodology of addressing this question. And  
19    I can't speak for Pfizer obviously as to why they  
20    choose not to use a meta-analysis. But there is no  
21    one that I'm aware of.

22          Q.     You do agree, sir, that both Miles and  
23    McDonagh are both published peer reviewed meta-  
24    analyses that looked at Zoloft and cardiac birth  
25    defects, right?

1           A.    Yes, certainly Miles is, and I think that  
2   McDonagh was part of a very large report, which was  
3   published. I don't remember the peer review status of  
4   McDonagh.

5           Q.    All right. Let's -- we'll come to it.  
6   Let's take a look at Miles. And let's look at their  
7   objective, okay? And that's from the Miles abstract.  
8   And we'll put it out.

9                   Miles' objective was to determine the  
10   strength of the association between individual SSRIs  
11   and major/minor and cardiac malformation among infants  
12   born to women taking these medicines, right?

13          A.    You read it correctly.

14          Q.    And they followed a specific method, right,  
15   called Moose (ph)?

16          A.    They did.

17          Q.    Okay. And if we go to the -- continue on  
18   the abstract. The study found -- the meta-analysis  
19   found that for Zoloft and Celexa that they were not  
20   significantly associated with congenital malformation,  
21   correct?

22          A.    Yeah, I'm sorry, I can't follow on the  
23   screen, it's just blurred.

24          Q.    It's Miles' abstract. There it is. It just  
25   takes us a minute to pull it out, Doctor.

1           A.    Okay.  That's fine.  It's just when you're  
2   reading I can't -- I just wanted to let you know I  
3   can't follow along with you.

4           Q.    Okay.  So Sertraline and Citalopram were not  
5   significantly associated with congenital  
6   malformations, correct?

7           A.    You read that correctly, yes.

8           Q.    All right.  And in their section on page  
9   1007 reporting the results of cardiac malformations  
10   the report states that Zoloft was not significantly  
11   associated with increased odds of cardiac  
12   malformations, correct?

13          A.    Sertraline.  Sertraline, yes.

14          Q.    Well you know Sertraline is Zoloft, correct?

15          A.    Yes, that's correct.

16          Q.    All right.  But it did show that some of the  
17   individual agents, Paroxetine was significantly  
18   associated, correct?

19          A.    Paroxetine.  I've lost Paroxetine in this  
20   paragraph.  I'm sorry, I'm not following you.

21          Q.    I think it's right above.

22                   THE COURT:  Read the first sentence.

23                   THE WITNESS:  Oh, there it is.  Yes,  
24   it's -- I was looking for the ones at the bottom where  
25   the drugs are highlighted.



1 BY MS. YATES:

2 Q. I apologize, Doctor.

3 A. That's okay. Yes, Paroxetine was  
4 significantly associated in their meta-analysis with  
5 cardiac malformation.

6 Q. And that's Prozac?

7 A. That's Prozac, correct.

8 Q. All right. And the others were not,  
9 including Sertraline, which is Zoloft?

10 A. Correct.

11 Q. Okay. And in fact the authors conclude --  
12 well let's just take a look at figure 2, if we can.  
13 The meta-analysis reported an odds ratio of 0.931 for  
14 Zoloft and cardiac malformations, correct?

15 A. This is -- yeah, I'm not sure what you're  
16 pulling out here. You've got Pederson on the left  
17 there with numbers for CHD. Is that the Pederson  
18 results? And then underneath that, is that the meta-  
19 analysis?

20 Q. So, Doctor, these are all the study names,  
21 right? You know how meta-analysis goes, right?

22 A. I -- to be frank I just can't read this, the  
23 page.

24 THE COURT: I think he needs to refer  
25 to the hard copy.

1 THE WITNESS: Yeah, why not--

2 MS. YATES: All right. I think that's  
3 a good idea.

4 THE WITNESS: Sure. That's --

5 BY MS. YATES:

6 Q. Why don't you pull out the hard copy,  
7 Doctor.

8 THE COURT: And it is an appropriate  
9 time to take a brief recess in the morning, so we'll  
10 do that now, and come back with hard copies for all of  
11 us.

12 THE WITNESS: All right. Thank you.

13 (Recessed at 11:20 a.m.; reconvened at 11:43  
14 a.m.)

15 THE COURT: All set?

16 CROSS-EXAMINATION, CONTD.

17 BY MS. YATES:

18 Q. Hello again, Dr. Jewell.

19 A. Hi.

20 Q. Now you met with the lawyers during the  
21 break, but I assume you didn't talk about your  
22 testimony because you know you're under cross-  
23 examination, correct?

24 A. Do I have to say what I talked about?

25 Q. Well if you talked about your testimony you

1 weren't supposed to.

2 A. I asked the way to the bathroom and they --  
3 in the side there.

4 Q. No problem. You didn't know that from  
5 yesterday?

6 A. This is a big place, I'm not paying  
7 attention to the location of the restrooms.

8 Q. Okay. But you didn't talk about your  
9 testimony?

10 A. No.

11 Q. Okay. We left off, Doctor, at Miles, figure  
12 2 and the result for Zolofit. So, I think you have  
13 that now in hard copy, but we also were able to pull  
14 it out. All the studies are listed, right, Doctor,  
15 with the results, and they plot the odds ratios and  
16 the confidence intervals, rights, and then they have a  
17 final result for Zolofit, correct?

18 A. Correct.

19 Q. And that odds ratio for Zolofit is .931,  
20 correct?

21 A. Correct.

22 Q. And that's cardiac malformations?

23 A. Correct.

24 Q. And in fact if we turn to page 1011 you said  
25 yourself that when the studies are done you've got

1       your statisticians and then you've got your medical  
2       people, right?

3           A.    I don't know in this particular case who's  
4       involved.

5           Q.    Okay. Well we could look, right?

6           A.    Well we know the authors names, yes.

7           Q.    Right. And some of those are medical  
8       doctors?

9           A.    You know I haven't looked, I don't know. I  
10       don't know -- these are from New Zealand I think. I  
11       don't know them.

12          Q.    Right. They have doctors in New Zealand,  
13       right?

14          A.    I assume.

15          Q.    Assume some of them -- do we need to look to  
16       see if there are medical doctors on Miles?

17          A.    It's up to you, I'm in your hands. Whatever  
18       you would like.

19          Q.    Why don't you look.

20          A.    So it doesn't tell me on the authors who's a  
21       doctor and who isn't.

22          Q.    But it usually has a little reference, and  
23       then you see their institutions they're associated  
24       with or M.D., Ph.D.

25          A.    Yeah, it's -- well --

1 Q. Doctor, it doesn't -- I went down that track  
2 because I didn't think we were going to debate it.

3 A. Okay.

4 Q. If you can't find it --

5 A. I found it now, yes.

6 Q. Okay. All right. And there are doctors?

7 A. They're from the departments of medicine and  
8 then from obstetrics and gynecology and from  
9 psychiatry in -- actually they're in Australia, so we  
10 ought to correct that, they're not from New Zealand.

11 Q. Okay. All right. So if we go to page 1011  
12 some of those -- the authors of the study, including  
13 people from the department of obstetrics, gynecology,  
14 and psychiatry actually conclude -- page 1011 -- that  
15 the alternative first line SSRI medications,  
16 Sertraline or Citalopram, should be considered as  
17 first line SSRI treatments in pregnancy and women of  
18 child-bearing age. Did I read that correctly?

19 A. You did.

20 Q. And in the Miles meta-analysis following  
21 their peer reviewed published methodology that's the  
22 conclusion they made, correct?

23 A. I assume they made that conclusion since  
24 it's in the paper.

25 Q. And you disagree with them?

1 A. No, I don't disagree with that necessarily.

2 Q. All right. Let's move to McDonagh.

3 A. I'd be happy to explain why, but -- that  
4 particular sentence is not something that intersects  
5 with my report that much.

6 Q. Okay. Let's move to McDonagh. July 2014  
7 the agency for health care research and qualify,  
8 that's a branch of the Department of Health and Human  
9 Services, right?

10 A. That is correct.

11 Q. And this is a meta-analysis that examined,  
12 among other things, the risk of cardiac malformations  
13 associated with Zolofit use during pregnancy?

14 A. It did, briefly, yes.

15 Q. All right. And if we go to table 6, Doctor,  
16 and I think we've seen this before. Table 6, the  
17 meta-analysis found -- actually page 45, I'm sorry. A  
18 quote from page 45. Found that they pooled analysis  
19 --

20 A. Sorry, can I just --

21 Q. Yeah.

22 A. -- interpret you for a second?

23 Q. Sure.

24 A. You said page 45, but there is no table on  
25 page 45, so if you --

1 Q. Right. We're going to come back to table 6.

2 A. Oh, I'm sorry.

3 Q. I apologize.

4 A. You've moved around here, okay.

5 Q. I absolutely did.

6 A. Great.

7 Q. Page 45, Sertraline.

8 A. Yes.

9 Q. With me? This meta-analysis first found  
10 that pooled analysis of the seven studies that  
11 reported adjusted odds ratios resulted in no increased  
12 risk of cardiac malformations (table 6) but with  
13 statistical heterogeneity. Did I read that correctly?

14 A. You read that correctly.

15 Q. And so McDonagh actually did a further  
16 analysis to try to account for and look into this  
17 heterogeneity, right?

18 A. She tried to -- or she or he tried to remove  
19 it by doing a sensitivity analysis by looking at fewer  
20 studies.

21 Q. Right.

22 A. Which will of course inevitably reduce  
23 heterogeneity systematically as you peel them off.

24 Q. So they got that right. They're looking to  
25 reduce heterogeneity and they followed what you said

1 is a way to reduce heterogeneity.

2 A. Not really. It depends very much on how you  
3 select your approach to reducing heterogeneity.

4 Q. Okay.

5 A. My report says the right way to look at the  
6 statistical heterogeneity is try and determine the  
7 factors that explain the heterogeneity, because then  
8 you will have some knowledge about what the  
9 characteristics are of women in studies who show an  
10 increased risk and what the different characteristics  
11 might be in studies which show no risk, and that's not  
12 what they're doing.

13 Q. Well let's --

14 A. So this is not exactly what I would do, no.

15 Q. Not exactly what you'd do, but it's what  
16 they did?

17 A. It is what they did apparently, yes.

18 Q. And they published it and they subjected it  
19 to peer review, correct?

20 A. Yes, they --

21 Q. All right.

22 A. -- some -- as I said this -- early this  
23 morning, I'm not sure of the level of peer review on  
24 this publication.

25 Q. Okay. Let's look at the next sentence where



1 we talk about this sensitivity analysis, okay, Doctor?

2 Sensitivity analysis, first removing two  
3 studies that did not adjust for at least three of the  
4 four potential confounding factors identified for this  
5 review, resulted in a pooled estimate suggesting a  
6 reduced risk of cardiac anomalies with Sertraline  
7 (pooled adjusted odds ratio .76, 95 percent confidence  
8 interval, .59 to .97), but further limiting to the  
9 four studies that also indicated efforts to identify  
10 serious cardiac malformations yielded a pooled  
11 estimate of .76, 95 percent confidence interval, .57  
12 to 1.0 P value .51. Actually that should be .051,  
13 right, Doctor?

14 A. It's certainly wrong, but that sounds  
15 plausible that it's just clipping -- it's just not  
16 significant.

17 Q. Okay. So the McDonagh authors concluded no  
18 increased risk or suggested a reduced risk for cardiac  
19 anomalies with Zoloft, correct?

20 A. That is correct, that's what they claimed.

21 Q. And you disagree with them?

22 A. I do disagree. Not so much with the  
23 findings per se, I disagree with the methodology that  
24 they used and the data they applied to reach that  
25 conclusion in light of what I myself have done, yes.

1 Q. Okay. Now if we go to table 6 now, which is  
2 page 44, the title of this table is, best evidence on  
3 risk of cardiac malformations with selective Serotonin  
4 reuptake inhibitors compared with non-exposure. Did I  
5 read that correctly?

6 A. Correct.

7 Q. And their finding for Sertraline or Zoloft  
8 is 1.08, confidence interval is .70 to 1.65, correct?

9 A. Yes, that is correct, you read it correctly.

10 Q. And because of the heterogeneity they did  
11 the sensitivity analysis, correct?

12 A. They did a sensitivity analysis, correct.

13 Q. And that yields the result of an odd ratio  
14 of .76, confidence intervals .57 to 1.0, correct?

15 A. Correct.

16 Q. All right.

17 A. That's the same number I think that you just  
18 read in the paragraph a minute ago.

19 Q. And so the table corresponds with the  
20 statements that they made is accurate?

21 A. That is correct.

22 Q. Okay. There's another meta-analysis, right,  
23 Dr. Wang 2015?

24 A. Yes.

25 Q. This one God smacked you?

1 A. It did.

2 Q. All right. Do we need to talk about Wang?

3 A. Well you -- I'm in your hands.

4 Q. Okay.

5 A. I'm happy to talk about it if you want.

6 Q. Let's briefly talk about Wang. Three

7 studies, right?

8 A. Three studies, correct.

9 Q. Peer reviewed and published?

10 A. Correct.

11 Q. And you disagree with it?

12 A. Again, it's not so much the results, it's  
13 the fact that there are only three studies included in  
14 the meta-analysis with no real explanation of why all  
15 the other studies, including some of the major ones  
16 we've discussed at length, were excluded.

17 Q. Okay. And you disagree with -- it adds  
18 nothing to you?

19 A. Well of course a meta-analysis I can do it  
20 of those three studies myself, so from that point of  
21 view it doesn't add anything new -- they don't provide  
22 any new statistical insights into the data about those  
23 three studies that I was not aware of before. So from  
24 that perspective, yes, it doesn't provide a lot, and  
25 it's so incomplete.

1 Q. Incomplete because there's a bunch of  
2 studies and they only did three, right?

3 A. And the particular choice of those three too  
4 in terms of where they sit in terms of updates and  
5 overlaps, yes.

6 Q. All right. Let's move to your report in the  
7 Prozac litigation, Doctor, because there you did focus  
8 your review on numerous meta-analyses that reviewed  
9 and analyzed data relating to maternal exposure to  
10 Prozac during pregnancy, right?

11 A. Well as I just discussed before the break I  
12 focused my analysis initially -- or my analysis began  
13 with in a sense the meta-analysis that was provided by  
14 Eli Lilly themselves in their own documents. And  
15 there are others, as I indicated earlier, that I also  
16 looked at, including Miles, for example, and I think  
17 even McDonagh was -- commented about Prozac also. So  
18 those were also discussed in the report.

19 Q. Doctor, do you agree or disagree with the  
20 following statement. You focused your review on  
21 numerous meta-analyses that reviewed and analyzed data  
22 related to maternal exposure to Prozac during  
23 pregnancy?

24 A. I put -- I just answered that question, I  
25 believe. I focused my analysis initially on the Eli

1 Lilly meta-analysis, which is more complete than  
2 Miles, and then of course I included data from studies  
3 that were newer that were not incorporated in that.  
4 So, I focused my analysis on the entire body of  
5 evidence regarding the association between Prozac and  
6 cardiac birth defects.

7 Q. Tab 19, please. Doctor, this is page 5 of  
8 your Prozac report. Can we pull it out so everybody  
9 can read it, please.

10 A. Uh-huh.

11 Q. Let me know if I'm reading this correctly.

12 I focused my review on numerous meta-  
13 analyses that reviewed and analyzed data related to  
14 maternal exposure to Prozac during pregnancy. Did I  
15 read that correctly, sir?

16 A. You read that correctly.

17 Q. All right. And your review of meta-analyses  
18 included Miles and McDonagh?

19 A. Yes, as I just said, yeah.

20 Q. Okay. And let's look at your Prozac report  
21 on your findings from the Miles investigators. It's  
22 page 20 of your Prozac report. Okay. All right.

23 You say, existing -- these are the findings  
24 of Miles -- or at least this is based on the findings  
25 of Miles, right?

1           The existing research appears to implicate  
2   Fluoxetine and Paroxetine. This suggested that  
3   neither Paroxetine nor Fluoxetine should be used  
4   electively as first line antidepressant therapy, and  
5   those wishing to become pregnant or in the first  
6   trimester of pregnancy.

7           Did I read that correctly?

8           A. Yes, this is a quote from Miles, if I  
9   understand it correctly.

10          Q. Quote from Miles.

11          A. In my report, yes.

12          Q. Right.

13          A. Okay.

14          Q. And then you've got a dot, dot, dot, right?

15          A. Correct.

16          Q. And Mr. Zonies told us yesterday that the  
17   dot, dot, dot is very important, so let's look at  
18   what's --

19          A. Sure.

20          Q. -- dot, dot, dot. Let's go to Miles. And  
21   the dot, dot, dot actually says, "When Sertraline or  
22   Citalopram might equally be prescribed." Right?

23          A. It does, yes.

24          Q. Okay.

25          A. I don't see the point there. It's -- this

1 is a report about Prozac. I think the sentence is  
2 perfectly clear, but be that as it may.

3 Q. Okay. You in fact comment that that's quite  
4 a strong statement. It's significant enough for those  
5 authors to make that statement. In other words saying  
6 don't use these as first line, use these, right? You  
7 said that's a strong statement.

8 A. That's the statement the authors made, yes.

9 Q. All right. Now we heard this briefly so I'm  
10 going to try and just sum it up, Doctor, but instead  
11 of focusing on meta-analysis in your Zoloft report  
12 like you do in your Prozac report, one of the reasons  
13 that you don't focus on Miles in Zoloft is the  
14 methodological flaws, correct?

15 A. Correct. Correct.

16 Q. And you say in your report you don't find  
17 Miles scientifically reliable, right?

18 A. In terms of the results that you've spent  
19 some time reading a minute ago I think they're  
20 misleading to the Court and to people listening,  
21 because they're not reliable in the context of the  
22 whole body of evidence.

23 Q. All right. So actually if they're  
24 misleading in this court and you think they've gotten  
25 them wrong they're out in the peer reviewed published

1 literature, so anybody who picks it up is going to be  
2 misled by a peer reviewed published meta-analysis done  
3 by Miles. That's your opinion?

4 A. I think if they're interested specifically  
5 in the question of Zoloft and cardiac defects there's  
6 more room for misinterpretation because of the  
7 heterogeneity that we discussed yesterday. There's  
8 less room for misinterpretation with regard to Prozac,  
9 because there's far less heterogeneity in the results  
10 that Miles presents for Prozac.

11 So again, it's a contextual answer. The  
12 whole paper is not entirely misleading from beginning  
13 to end, and as I said, anyone can do their own meta-  
14 analyses of the studies that Miles considered, should  
15 they wish.

16 Q. And, Doctor, in the Prozac litigation, in  
17 that report, you refer to methodological limitations  
18 of Miles, correct?

19 A. Yes. And as we discussed yesterday, there  
20 was this confusion about the inclusion/exclusion  
21 criteria that Miles used that still remains  
22 uncorrected, as far as I'm aware, and the issue of  
23 heterogeneity.

24 Q. Sir, there's an affidavit from Dr. Large,  
25 one of the coauthors of the Miles study, saying they



1       used the appropriate inclusion/exclusion criteria and  
2       you got it wrong, right? You've seen that affidavit?

3           A.     I did. And as I pointed out at the  
4       deposition when that was presented to me, that his  
5       statements -- and I think we discussed this yesterday  
6       -- his statements and the statements in the paper are  
7       contradictory. He has now apparently, I didn't know  
8       this, but from emails between your counsel, and he has  
9       agreed that it was written badly. We should look at  
10      the emails to use his language, but he has written it  
11      badly and maybe he should send a correction. I think  
12      that's the last I've heard of the story, but I don't  
13      know if a correction has appeared or not.

14           Q.     So it's wrong in the peer-reviewed published  
15      and he got it wrong again when he said you were wrong?

16           A.     In the affidavit, because as we discussed  
17      yesterday the paper specifically says the exclusion  
18      referred to excluding studies where some of the women  
19      in the control group were exposed to other  
20      antidepressants, in the affidavit he claimed that the  
21      inclusion/exclusion criteria used/excluded only  
22      studies where all of the women in the control group  
23      were not exposed to antidepressants. So it doesn't --  
24      and as I've said many times, it doesn't really -- you  
25      know, it's essential, I'd just like him to tell me

1        what the actual inclusion/exclusion criteria area. To  
2        some extent, with all the new studies that have  
3        appeared Miles it's somewhat moot, because one  
4        wouldn't do a meta-analysis today, even if that were  
5        appropriate, on the studies that Miles used.

6            Q.     Doctor, let's go back to McDonagh. Let's go  
7        to page 22 of your Prozac report, if we can, and how  
8        you describe McDonagh.

9            (Pause)

10          Q.     All right. Again, this is your Prozac  
11        report referring to McDonagh. This is a report issued  
12        in July, 2014 and its stated objectives were "to  
13        conduct a systematic review to evaluate the benefits  
14        and harms of various pharmacological treatment options  
15        for depression during pregnancy and the post-partum  
16        period compared with each other with non-  
17        pharmacological treatments and with usual care or no  
18        treatment. I focused my evaluation and review on the  
19        Prozac-specific findings related to cardiac  
20        malformations and somewhat to major malformations  
21        overall. The sources of data review and study  
22        selection process were done through literature  
23        searches and review of abstracts and publications.  
24        Case reports, case series and single-group studies  
25        were excluded from the evaluation."

1 Did I read that correctly?

2 A. You read that correctly.

3 Q. Now, that's not how you describe McDonagh in  
4 your Zolofit report, correct? Let's look at that.

5 A. Actually, I don't think McDonagh was in my  
6 original report at all, but --

7 Q. That's fair. We discussed it and it came  
8 back --

9 A. Yes.

10 Q. -- and came in later.

11 A. Yes, because people wanted me to say  
12 something about McDonagh.

13 Q. Okay. Well, let's look at what you say on  
14 McDonagh and in your Zolofit report, in your updated  
15 report. "An additional meta-analysis was also carried  
16 out by McDonagh 2014 for the Agency for Healthcare  
17 Research and Quality. This is another meta-analysis  
18 suffering from methodological problems regarding how  
19 studies were included and excluded. Due to the  
20 study's brief section on Sertraline and cardiac birth  
21 defects consisting of only three sentences, it is  
22 impossible to fully assess the author's methodology."

23 Did I read that correctly?

24 A. That is correct.

25 Q. All right. Well, let's go and look at the

1 section on -- part of the reason you reject it on  
2 Zolofit is there's only three sentences. What on earth  
3 can we conclude from three sentences, right?

4 A. No, I just am trying to point out there --  
5 and I'm not a big fan of McDonagh, I don't think  
6 that's a surprise to anyone in this room --

7 Q. It's no surprise to me.

8 A. -- whether I'm talking about Prozac or  
9 talking about Zolofit -- what I'm pointing out there,  
10 it's a very brief part of a much larger report.

11 Q. Right.

12 A. And to be fair to the authors, they were  
13 trying to study many, many questions, and so they were  
14 not able to describe their methodology in detail in  
15 the way you would expect in a paper like Miles, for  
16 example, or Wang for that matter, and they only have  
17 three sentences to do it. If you go into the body of  
18 the report, you can -- in the Prozac I said this is  
19 how they came up, as far as I understand it, with  
20 their studies, seven in the case of Prozac, that's all  
21 I'm saying.

22 Q. So it was brief, it was three sentences, not  
23 enough for you to evaluate, right?

24 A. Well, I think it's -- when you're reviewing  
25 a meta-analysis, as we've just spent some time talking

1 about with Miles, you would like to understand the  
2 inclusion/exclusion.

3 Now, as it happened with Zoloft, I was  
4 sufficiently familiar with all of the studies that  
5 could have gone into a meta-analysis to recognize in  
6 the references and their footnotes the seven studies  
7 they were using, but they don't describe why these  
8 seven, they don't tell me in the reduction that you  
9 spent some time going down when they did a sensitivity  
10 analysis, they're not explicit about how they -- which  
11 studies they removed. And so that actually made it  
12 hard to reproduce on my own any meta-analysis that  
13 could reproduce McDonagh as a result, because it's  
14 just -- they don't have enough space and they haven't  
15 described it. That usually wouldn't be satisfactory  
16 if you had a paper about Zoloft and cardiac birth  
17 defects.

18 Q. I understand. So not enough information on  
19 Zoloft, but you did have enough information on Prozac  
20 to --

21 A. There's the same --

22 Q. -- at least assess, right?

23 A. There's the same information in both, it's  
24 got the same level of quality. The fundamental  
25 difference in both Miles and in McDonagh comparing

1       Zoloft and Prozac is the heterogeneity of the  
2       information. The heterogeneity of the information is  
3       clearly statistically significant in Miles, it's not  
4       in Miles for Prozac. That's the difference, the  
5       fundamental difference. But with regard to the  
6       quality of the meta-analysis per se, it's the same for  
7       both. I have never tried to claim anything other than  
8       that.

9           Q.     Are we talking about McDonagh or Miles?

10          A.     We were talking about Miles. If you want to  
11       say McDonagh, there's the same issue occurs in  
12       McDonagh too.

13          Q.     Okay, Doctor, I think this is referring to  
14       McDonagh when you talk about the three sentences.

15          A.     Yes. Now, if you turn to table 6 on page  
16       44, if you could put that up on the screen for us?

17          Q.     Already been there.

18          A.     Could you put it up on the screen so I  
19       can --

20          Q       Sure, absolutely. The table 6 that we  
21       already discussed that has the two results, one before  
22       the sensitivity --

23          A.     Table 6 on page 44. It was up a minute ago.

24          Q.     Doctor, I promise you, I won't talk over  
25       you, if you won't talk over me.

1           A.     That's fine. I'm just asking for table 6 on  
2     page 44, it's --

3           Q.     Right. And table 6 is the "Best evidence"  
4     table, right, that one?

5           A.     It's the one you just put up to read and  
6     comment on.

7           Q.     Let's put it up again.

8                   MS. YATES: If they're relying on me to  
9     find something, Your Honor, we're in trouble. It is -  
10    -

11                  THE WITNESS: Well, I can read from it,  
12    if you want. I have it right in front of me.

13                  MS. YATES: No, let's put it up, so the  
14    Court can see it as well.

15                  THE COURT: Well, I'm looking at a hard  
16    copy too.

17                  MS. YATES: Are you? Okay.

18                  THE WITNESS: Okay, great. So --

19                  THE COURT: My eyes are not adjusting  
20    to the filmy program, it's very hard to read this.

21                  MS. YATES: It's hard to read on --  
22    yeah.

23                  THE COURT: It's much harder than  
24    yesterday and I don't know if it's just a programming  
25    issue with working through the court system or not,

1 but it's hard. So I've resorted to paper, just like  
2 our witness.

3 MS. YATES: And I'm struggling a little  
4 bit, Your Honor, as you can tell when I look at the  
5 screen. So I'm tending to multitask here. Okay.

6 THE WITNESS: There it is.

7 BY MS. YATES:

8 Q. So table 6 that we already discussed, right,  
9 Doctor?

10 A. Yes. Now --

11 Q. And this is --

12 A. Wait a minute, I was --

13 Q. I'm sorry, I get to ask questions.

14 A. I think I was making the point, though. I  
15 wasn't waiting for a question, I wanted to bring this  
16 back up --

17 Q. Oh, I'm sorry.

18 A. -- in reference to my answer, and my answer  
19 was, the fundamental difference in Miles was the  
20 heterogeneity and you said -- interrupted and then  
21 said, but that's Miles, we're talking about McDonagh.  
22 So here's the table, it gives us information about  
23 heterogeneity from McDonagh. And you can see in the  
24 right-hand column, the heterogeneity, I won't bore you  
25 with what the i-squared statistic is, but it's -- the



1 larger it is, the more heterogeneity there is.

2 For Sertraline, you can 68 percent in  
3 that column, meaning the results that led to that  
4 meta-analytic odds ratio vary substantially, there's  
5 some much lower than 1.08 and there's some much  
6 higher. And you can see from Prozac or Fluoxetine,  
7 the heterogeneity is zero percent, it's actually also  
8 zero percent for Paroxetine and Paxil, meaning there's  
9 very little heterogeneity. That's fundamentally the  
10 reason why you might treat the data differently for  
11 Zoloft than you might for Prozac or, for that matter,  
12 for Paxil.

13 Q. And, Doctor, we went through this, but just  
14 to be clear, the reason there is a sensitivity  
15 analysis under Sertraline is because of the finding of  
16 heterogeneity, correct?

17 A. That's one reason they did it, it's not the  
18 reason they -- the sole reason they did it.

19 Q. Okay, one of the reasons.

20 A. Correct.

21 Q. And when they did the sensitivity analysis,  
22 the heterogeneity goes to zero percent, correct,  
23 Doctor?

24 A. Well, do you really think that's a plausible  
25 way to deal with heterogeneity? The issue -- how they

1        dealt with heterogeneity here is they simply took the  
2        low values of the odds ratio, the ones that were most  
3        alike, of course the heterogeneity goes away. A grade  
4        school student could do that, just put the red blocks  
5        together. That's not a statistically sophisticated or  
6        appropriate way to deal with heterogeneity. Let's  
7        just find a way to get the results in the meta-  
8        analysis to a point where they all look alike and  
9        throw the other ones out, that is not to me an  
10       appropriate methodology. Anyone could do that. As I  
11       said, as you remove studies, systematically that 68  
12       percent there, as you go from seven to six, will go  
13       down. Whatever one you pick, if you take two out, it  
14       will go down some more. It will go down a lot if you  
15       hand pick -- I'm not going to say cherry pick, but if  
16       you hand pick the studies, in this case I think it was  
17       four of the seven, they picked -- or they ended up  
18       with the four that were the most similar, so the  
19       heterogeneity is gone. That's why they get this kind  
20       of strange result that Zolof is protective for  
21       cardiac birth defects. There's not a single other  
22       paper that I have read that suggests anywhere that  
23       Zolof reduces the risk of a cardiac birth defect by  
24       24 percent.

25                                So it's just not a plausible

1 methodology in this meta-analysis to hand pick four  
2 studies that look the same, that all have low values,  
3 and get rid of the heterogeneity. That's actually  
4 what I was trying to get at yesterday where averaging  
5 can really obscure the truth. It's just not  
6 appropriate methodology.

7 Q. Sir, I'm not a mathematician, I couldn't do  
8 this, and if I look at sensitivity analysis that is in  
9 the table you wanted me to bring up, I see a zero  
10 percent heterogeneity after the sensitivity analysis.  
11 Did I read that correctly?

12 A. As I indicated, you read that correctly.  
13 And I think you understand now why I feel so strongly  
14 that that's an inappropriate way to deal with  
15 heterogeneity.

16 Q. Have you written to the journal saying this  
17 is wrong, this is ridiculous, a grade school student  
18 could do it?

19 A. I'm working my way through the places that  
20 Pfizer suggests I write to. It would be much more  
21 powerful, in my opinion, if Pfizer themselves, now  
22 that you understand why this is misleading, if Pfizer  
23 themselves would take on this, it would have much more  
24 weight than I. I've already -- I'm working my through  
25 it. I've contacted the FDA, I'm contacting

1 Huybrechts. I will get to this if you wish me to, but  
2 I'm -- you know, I have 24 hours a day.

3 Q. You've contacted the FDA?

4 A. I have asked for my report to be sent to the  
5 FDA, yes, because Pfizer urged -- asked me that same  
6 question at trial. You feel strongly about this, you  
7 have an opinion about causation, have you told the  
8 FDA? I answered truthfully that I had not at that  
9 point. As soon as the trial was over, I asked counsel  
10 if they would be willing to release my report to the  
11 FDA, which I believe they did.

12 Q. Do you know if counsel has released your  
13 report to the FDA, sir?

14 A. You would have to ask counsel to confirm  
15 that, not me, because I didn't physically put it in an  
16 envelope, but I asked them to do so. Now, they told  
17 me they did, but you'd have to confirm with them.

18 Q. Do you have a communication from counsel  
19 indicating that they have sent it to the FDA?

20 A. You'd have to ask counsel the  
21 communications.

22 Q. No, I'm asking --

23 A. They've told me verbally.

24 Q. I'm asking you if you have written  
25 communication from counsel confirming that they've

1 submitted your report to the FDA?

2 A. They have told me verbally on multiple times  
3 when I have asked.

4 Q. So you don't have anything written?

5 A. I don't have anything written, they may well  
6 have something written.

7 Q. All right, let's go back to where we were  
8 before we went back to table 6. So we were back  
9 discussing the fact that you're clearly critical of  
10 the methodology in McDonagh and part of your criticism  
11 was also that there's only three sentences on it,  
12 right --

13 A. But I'm not a big --

14 Q. -- we were there?

15 A. -- I'm not a big fan of the meta-analysis  
16 for either Prozac or for Zoloft, that is correct.

17 Q. All right. Well, let's take a look at  
18 McDonagh and the section on Prozac, because you did  
19 review and comment on it in your report on Prozac as  
20 part of your review. So if we go to Fluoxetine,  
21 Prozac, that's the entire section, Doctor, on  
22 Fluoxetine, correct?

23 A. Is this a quote or from my report? I'm  
24 sorry, I lost you a little bit.

25 Q. I'm sorry, this is actually from McDonagh.

1 So if you want the hard copy, it's under M for  
2 McDonagh.

3 A. Your Honor, I have the paper, is that -- I  
4 can't read the page numbers.

5 THE COURT: Isn't that the same page as  
6 table 6?

7 MS. YATES: Your Honor, that's a very  
8 good question.

9 THE COURT: I think it is.

10 MS. YATES: 44 to 45, yes, it is.

11 BY MS. YATES:

12 Q. Doctor, you should be there.

13 A. I'm on 46 with the table, but --

14 THE COURT: Right below it.

15 MS. YATES: Right below it.

16 THE WITNESS: Okay.

17 BY MS. YATES:

18 Q. That is the entire section --

19 A. Oh, table 6. Okay, I got it. Thank you.

20 Q. That's the entire section in McDonagh on  
21 Prozac, correct?

22 A. Correct.

23 Q. All right. I counted five sentences.

24 A. On Prozac?

25 Q. Yes.

1 A. Yes.

2 Q. I actually counted 128 words. Are you with  
3 me?

4 A. I'm sure.

5 Q. Okay. Let's look at the Sertraline or  
6 Zoloft section from McDonagh. That's the entire  
7 section on Sertraline, right?

8 A. Correct.

9 Q. Three long sentences?

10 A. As I indicated, yes.

11 Q. All right.

12 A. I did that counting.

13 Q. 143 words, I did that counting.

14 A. I didn't do that one.

15 Q. All right.

16 A. Key distinction, heterogeneity. Just think  
17 heterogeneity every time you go back to Prozac and  
18 Zoloft.

19 THE COURT: I think we're going to wait  
20 for a question.

21 BY MS. YATES:

22 Q. I'm not thinking heterogeneity, Doctor, I'm  
23 thinking what happens when they do a sensitivity  
24 analysis because of heterogeneity, right? They  
25 recognized the issue and they did something to try and

1 correct for it, that's what's in my mind.

2 A. Yes, but you have to do it appropriately.

3 Q. They did it wrong?

4 A. You have to use the appropriate methodology.

5 Q. Understood. You think they did it wrong?

6 A. I think it's misleading the way they did it,  
7 yes.

8 Q. Now, if I'm just -- if I applied your  
9 methodology and I looked at Miles and McDonagh, you  
10 know, if I focused on meta-analyses, as you did in  
11 Prozac, but now I'm going to do it in Zoloft, you  
12 would not be able to conclude that Zoloft increases  
13 cardiac -- the risk of cardiac defects, correct, if we  
14 just looked at the meta-analyses?

15 A. At the individual studies in the meta-  
16 analysis or just the summary results?

17 Q. The meta-analyses.

18 A. The summary results.

19 Q. The meta-analyses.

20 A. Well, the meta-analyses involve individual  
21 studies. Are you saying if I just focused on the  
22 summary results in --

23 Q. The results that refer to the studies in the  
24 meta-analyses, correct.

25 A. If you -- let me put it in my own words. If



1     you relied solely on the summary results, the meta-  
2     analytic averages that Miles and McDonagh report, you  
3     certainly would not conclude that Zolofit causes  
4     cardiac birth defects. If you looked deeper at the  
5     individual studies, you might come to a somewhat less  
6     definitive opinion. And when you looked at all the  
7     data, including the studies that are not included in  
8     Miles and McDonagh, which there are several major  
9     studies now, you would come I think to my opinion, at  
10    least I would come to my opinion.

11           Q. But you agree, Doctor, that the studies on  
12    Zolofit are equivocal, right? You've testified to  
13    that.

14           A. Well, there's no question, it's not every  
15    study coming in with the risk doubling and clear, I  
16    suspect we wouldn't be here if it was unequivocal.

17           Q. Right.

18           A. You must believe it's equivocal or you  
19    wouldn't be spending your time here. So of course the  
20    evidence is equivocal, that's why you need a  
21    statistician to assess and make inference from data  
22    which has uncertainty attached to it. That's what I'm  
23    trained to do and that's what I've tried to do in this  
24    case using appropriate methodology.

25           Q. Doctor, you testified with regard to

1 Avandia, correct, you sat in the witness chair?

2 A. Well, I couldn't remember exactly, as I said  
3 yesterday, but I did testify in a hearing about  
4 Avandia, yes.

5 Q. And in the Avandia litigation you also  
6 looked at meta-analyses, correct?

7 A. I did. And in that case there was a major  
8 meta-analysis -- now, this is -- my memory is now --  
9 this is going back quite a ways -- there was a meta-  
10 analysis, if I recall, by GSK, the manufacturer of  
11 Avandia, on -- they had several randomized clinical  
12 trials and they had done at various points meta-  
13 analyses as they got more trials in. And then there  
14 were some published meta-analyses in the literature by  
15 authors outside of GSK that were looking at similar  
16 questions, the Nissan (ph) meta-analysis and the Seng  
17 and Ferburg (ph) meta-analysis of Avandia and the risk  
18 of heart attacks and stroke.

19 Q. And in the Avandia hearing you told the  
20 court that "meta-analyses are useful because they are  
21 an appropriate way to combine information to see if  
22 there's a persistent pattern that adds up to something  
23 of concern that reaches statistical significance,"  
24 correct?

25 A. Yes. And in the context of randomized

1 clinical trials, that's certainly a true statement.

2 As I testified yesterday, the value of meta-analysis  
3 in randomized clinical trials is that in a sense all  
4 studies are on an equal footing, at least with regard  
5 to compounding, because randomization removes the  
6 possibility of compounding, at least to some  
7 considerable extent because of the randomization.  
8 That's one thing.

9 The other issue in the Avandia case  
10 that was clear is these were all small trials. None  
11 of the Avandia trials that I testified about were  
12 designed to look at the issue of does Avandia increase  
13 the risk of heart attacks. This is not similar to the  
14 current case where most of the papers we've been  
15 discussing have been targeted specifically, in fact  
16 you read out the objectives of some of them, that  
17 they're specifically looking at the safety of SSRIs  
18 and birth defects. The trials in the Avandia meta-  
19 analysis were not designed to do that. They were  
20 small efficacy trials to measure the effect of Avandia  
21 in treating diabetic patients, so you get very few  
22 heart attacks. And I went through this at great  
23 length in that litigation. That's where meta-analysis  
24 now starts to play a quite different role than it does  
25 here.

1                   So there are clear distinctions between  
2     the use of meta-analysis in the Avandia and the use of  
3     meta-analysis here. In both cases they should be done  
4     appropriately, of course, and any methodology can be  
5     misappropriated.

6           Q.     Doctor, do you remember my question?

7           A.     I do. You asked me about my testimony and  
8     using -- did I use meta-analyses in my work on  
9     Avandia, and I said yes and here's what I did and why  
10    I used meta-analyses in that litigation.

11          Q.     Let me ask my question again, because that  
12    wasn't my question. Didn't you tell the court in  
13    Avandia that "meta-analyses are useful because they  
14    are an appropriate way to combine information to see  
15    if there is a persistent pattern that adds up to  
16    something of concern that reaches statistical  
17    significance"?

18          A.     Yes, and that's as I -- I did hear your  
19    question correctly and that's what I answered. In the  
20    context of that report where you're reading from,  
21    that's a context of randomized clinical trials, all  
22    small, with regards to detection of heart attacks. If  
23    you -- I don't know if the Judge's memory is any  
24    better than mine or yours, but in the Avandia  
25    litigation most of the clinical trials or many of them

1 had zero heart attacks. That would be equivalent in  
2 this litigation of looking at a study --

3 Q. Doctor --

4 A. -- of Zoloft and cardiac birth defects in  
5 which there were no cardiac birth defects observed.  
6 So it's a quite different context. In the context of  
7 randomized clinical trials, each of which have very  
8 little information on the outcome, very few heart  
9 attacks in the Avandia case, you're almost obligated  
10 to turn to something like a meta-analysis. All I'm  
11 saying in addressing your question is that's the  
12 context where that statement it's useful to use meta-  
13 analysis to combine studies, many of which have zero  
14 outcomes, into seeing whether there's something  
15 signal. That was the approach done by GSK, by Nissan  
16 and by Seng and Ferburg. That's a different context  
17 from where we are today in this particular litigation.

18 Q. So in Avandia you relied on and analyzed  
19 meta-analyses, in Prozac you relied on and analyzed  
20 meta-analyses, and in Zoloft you looked at them and  
21 you said no, correct?

22 A. No, that's I would say a mischaracterization  
23 of my methodology. I looked at the meta-analysis in  
24 the Zoloft litigation, they're covered in my report.

25 Q. And you've said in your testimony you've

1 rejected them?

2 A. If you could just let me finish and then --  
3 that would be okay?

4 Q. Absolutely.

5 A. So you said I did something differently in  
6 the three settings, Avandia, Prozac and Zoloft. In  
7 all three of them, there were meta-analyses done by  
8 other individuals. In Avandia, I actually did my own  
9 meta-analysis in addition. In all three of them I  
10 took accounting of their methodology, their findings,  
11 their insights. And in sum, as I discussed at the end  
12 of my testimony yesterday, you ought to be situational  
13 to the extent you can tell the difference between  
14 context, you ought to be able to tell the difference  
15 between in Avandia you're dealing with randomized  
16 clinical trials and in Zoloft you're dealing with  
17 observational studies.

18 You shouldn't treat meta-analyses and  
19 interpret them as a statistician exactly the same way  
20 in both those contexts, any more than, as you pointed  
21 out earlier this morning, you shouldn't treat an  
22 observational study the same way as you would treat a  
23 randomized clinical trial. You're going to use  
24 different statistics. It doesn't mean I ignored the  
25 meta-analyses in any one of these litigations or in

1 any of my other professional work, it's just you've  
2 got to interpret them and take account of their value  
3 and quality in the context.

4 Q. Doctor, there were also observational  
5 studies in Avandia that you looked at?

6 A. Well, we're going back about ten years. My  
7 memory is I didn't look at the observational studies  
8 in Avandia. But I'm happy to be corrected, but that  
9 was my memory.

10 Q. Let's go to -- let me just show you some  
11 testimony and see if it refreshes your recollection,  
12 in Avandia.

13 A. Sure.

14 Q. Let me see if I can do this.

15 MS. YATES: Your Honor, may I approach?

16 THE COURT: You may.

17 BY MS. YATES:

18 Q. It's tiny print, I apologize, but this was  
19 your Avandia testimony before Judge Rufe, In re  
20 Avandia. And so you're talking about, "We are  
21 fortunate because there are randomized controlled  
22 trials," right? We talked about that. And then  
23 subsequently, "then I would go on and look for  
24 information about the observational studies." Does  
25 that refresh your recollection that there are a number

1 of observational studies?

2 A. Oh, there certainly were, I have no -- there  
3 are certainly a number of observational studies about  
4 Avandia, but the body of my report and my testimony  
5 before Judge Rufe was about the randomized clinical  
6 trials.

7 Q. Oh, but you did review them, right?

8 A. I did review them, but I didn't put them in  
9 my report. I focused my report, to use your words, on  
10 the randomized clinical trial information, for which  
11 there was a lot, there were a lot of random -- there  
12 were close to 50, if my memory is correct, of  
13 randomized clinical trials. That was the focus of my  
14 report and that's my memory. I didn't spend any of my  
15 report discussing the observational study information,  
16 they're clearly is some.

17 Q. Right. And so -- okay, I'm not going to  
18 belabor it.

19 All right, let's go back to see if we  
20 can agree. You advised the Court in Avandia that  
21 "there are formal techniques in a meta-analysis that  
22 are designed to make sure studies are weighted  
23 properly." You agree with that, right?

24 A. Yes, there's -- meta-analysis is an  
25 averaging processing, as I indicated, and it's going



1 to weight different studies --

2 Q. Right.

3 A. -- differently because of the -- you know,  
4 for example, sample sizes can be substantially  
5 different.

6 Q. Because the little guys don't have the same  
7 weight as the big studies?

8 A. That's a nice way of putting it, yes.

9 Q. Okay. "And these techniques make sure that  
10 you don't make the improper mistakes of averaging  
11 results, so that no study has an undue influence,"  
12 correct?

13 A. It should have its influence based on the  
14 weighting scheme, which is usually a sample-size  
15 driven scheme, but not always, sometimes it's a little  
16 bit more sophisticated.

17 Q. And you've testified in this case that you  
18 can't do a meta-analysis because of this  
19 heterogeneity, correct?

20 A. Well, I'm not saying you can't do it, you  
21 can, it's just you have to be very careful in  
22 interpreting it because the averaging that is  
23 involved, weighting or not, can mislead you when you  
24 rely on the results of the summary when there's  
25 substantial variation in the individual trials.

1 Q. I just want to be accurate here.

2 (Pause)

3 Q. All right. Do you agree, Doctor, that based  
4 on the heterogeneity the problem that you have in  
5 Zolofit is that the averaging that meta-analyses does  
6 pretty much gets you nowhere, that's your opinion?

7 A. No, that's -- maybe -- that's not my words.  
8 I wouldn't say gets you nowhere, it's just you have to  
9 pay attention to the heterogeneity in interpreting the  
10 results that it gives. As I tried to make this clear  
11 yesterday, if you have two studies, one of which shows  
12 an odds ratio of two and one of which shows an odds  
13 ratio of 0.5, let's say equally weighted to make it  
14 simple, and you do a meta-analysis and you come out  
15 and report in the literature an odds ratio of 1 and  
16 interpret no risk, first of all, that's incorrect, an  
17 incorrect statistical interpretation, and it's clearly  
18 misleading because half of your women in the study had  
19 an odds ratio of 2. No one had an odds ratio of 1, as  
20 it happened. So that's why it's misleading. And, I  
21 mean, I can go on in greater detail as to why it's so  
22 misleading, but I thought that made it clear that in  
23 those kind of situations you can't resort to meta-  
24 analysis to resolve the inconsistency or the  
25 heterogeneity of the two studies.

1 Q. So let's take a look at your deposition. Do  
2 you remember having your deposition taken in a Zoloft  
3 case called Trace Foster? It was pending in St.  
4 Louis.

5 A. I don't recall, again, the details of the  
6 specific depositions.

7 MS. YATES: Your Honor, would you also  
8 like a copy of the transcript?

9 THE COURT: If you have it, yes.

10 (Pause)

11 THE WITNESS: Thank you.

12 MS. YATES: And we can put it up on the  
13 screen.

14 BY MS. YATES:

15 Q. And if you turn to page 103, Doctor,  
16 starting at line 7. Question, "You're perfectly  
17 capable of searching PubMed and a priori to find set  
18 of inclusion/exclusion criteria and accumulating the  
19 data the same way Miles and the same way McDonagh did,  
20 correct?"

21 Answer -- and the answer goes on for a  
22 bit, so bear with me -- "Well, but you're  
23 misinterpreting my answer. That certainly was not the  
24 obstacle. The obstacle is the data itself does not  
25 lend itself for a meta-analysis to be useful. The

1 meta-analysis is an averaging process. If you want to  
2 take an apple and an orange and average it, there's no  
3 obstacle to doing it, you can do it. You can take  
4 orange juice and apple juice and mix them together,  
5 there's no physical obstacle to doing it. Does it  
6 make sense? Sometimes averaging does. I've lived  
7 most of my life where averaging is terribly valuable,  
8 but the statisticians that have known for a long time  
9 that averaging can be horribly misleading. And in  
10 this case, with this amount of heterogeneity across  
11 studies, averaging gets you pretty much nowhere. So  
12 this is not a prime candidate for doing an effective  
13 meta-analysis, in my view."

14 Did I read that correctly?

15 A. You read that correctly and that's exactly  
16 what I said yesterday.

17 Q. Doctor, so you said there, when you've got  
18 this heterogeneity problem, it's like mixing apples  
19 and oranges, right?

20 A. Yeah, that would be like the 0.5 and the 2  
21 in my hypothetical example.

22 Q. Right. Do you recall that in Avandia you  
23 were asked about heterogeneity and whether it was like  
24 mixing apples and oranges?

25 A. I can't recall the details of the discussion

1       ten years ago.

2           Q.   Isn't it true, sir, that you told the Court  
3       that it's not like mixing apples and oranges, but  
4       rather mixing different types of apples?

5           A.   Well, I'd have to see the testimony.

6           Q.   Okay.

7           A.   It does sound like something I would say.  
8       And that would refer to -- the idea of apple and an  
9       orange is heterogeneity, right? An apple is quite  
10      different. If I held them in my hand, you could tell  
11      the difference, right?

12          Q.   I sure hope so.

13          A.   If I held two different varieties of an  
14      apple in my hand, could you tell the difference?

15          Q.   Possibly.

16          A.   But maybe not, right?

17          Q.   I could tell the difference in those wine  
18      glasses.

19          A.   Yeah, but that's an apple and orange. Let's  
20      not change the metaphor. If I had two apples,  
21      distinct varieties of apples, you probably couldn't --  
22      well, maybe they look enough the same, maybe I can  
23      combine these. That's exactly what I'm saying in this  
24      testimony here, that's exactly what I said yesterday,  
25      that's exactly what I'm saying now. When you're doing

1 a meta-analysis averaging, it's fine in all other  
2 things being equal to do it when you have no  
3 heterogeneity, because then the averaging is valuable,  
4 you're not mixing a 0.5 and a 2 and coming out with  
5 this distorted in-between value that no one  
6 experiences. And the value of meta-analysis, as in  
7 Avandia, is you get the increased precision that you  
8 get from combining multiple small studies.

9 So it's not that meta-analysis in  
10 itself is supposed to give you a magical different  
11 answer from the studies, that's not the purpose of  
12 meta-analysis. The purposes of meta-analysis, if done  
13 correctly, is to take homogeneous phenomena, each of  
14 which is imprecise, average them, and then you get a  
15 measure of the phenomena you're interested in, an odds  
16 ratio, but with much more precision. That's the point  
17 of averaging always, that's the point of meta-  
18 analysis, but you don't do it and mislead people when  
19 there's so much heterogeneity. That's what I said in  
20 this you just read me, that's what I said back in the  
21 Avandia case, that's what I said yesterday, and that's  
22 what I'm saying today.

23 Q. All right, Doctor, let's go to, I believe  
24 it's the same transcript, page 31.

25 MS. YATES: Is it the same transcript?

1 UNIDENTIFIED SPEAKER: No, that's  
2 (indiscernible).

3 MS. YATES: Oh, I'm sorry. It's not  
4 the same transcript, so I need another transcript.

5 BY MS. YATES:

6 Q. Doctor, we're now going to the Avandia  
7 transcript.

8 A. Okay.

9 Q. If you would turn to page 31, line 6.  
10 Question, "The other thing I wanted to ask you, is it  
11 like" --

12 A. I'm sorry, could you -- which page was it?

13 Q. I am so sorry. Page 31 --

14 A. 31, thank you.

15 Q. -- line 6.

16 A. Thank you.

17 Q. And actually we can -- you'll see on the  
18 middle of page 30, "Yesterday the word heterogeneity  
19 came up, right? So let's just give a little bit of  
20 context there."

21 Now we can go to page 31, line 6.

22 Question, "The other thing I wanted to ask you about,  
23 is it like mixing apples and oranges?"

24 Answer, "Well, of course the key thing  
25 in a well-conducted meta-analysis, one of the

1 limitations I think I refer to here is that the  
2 clinical trials that you are combining or  
3 observational studies, if it's a meta-analysis of  
4 observational studies, are not identical, they don't  
5 in fact one -- you can view that as a strength and a  
6 weakness. They are not identical population, they are  
7 not sampling from exactly the same population. The  
8 eligibility criteria for the trial that was designed  
9 for an efficacy reason may vary from trial to trial  
10 somewhat, they are done in different places.

11 "As I say, this is a weakness because  
12 you are now trying to mix things that were collected  
13 in different places. It's also a strength because, as  
14 we heard yesterday, one of the important issues in  
15 causation is seeing is a phenomena, is there any idea  
16 of a risk replicated in different populations, because  
17 that is going to strengthen your belief that this is  
18 something causal and not peculiar to a particular  
19 trial or a particular population.

20 "So one of the limitations, as I said,  
21 and strength is you are mixing these things. It's not  
22 mixing apples and oranges, however, if I can use that  
23 analogy, it's mixing different varieties of apples.  
24 All of these studies have the same drugs applied to  
25 the treatment arm, they were all by and large, with



1 some notable exceptions, studying diabetics, they were  
2 all essentially, when the data was pulled out on  
3 adverse events, they were -- all these investigators  
4 were honestly, I think, trying to get at the same  
5 question. So this was not really trying to pull  
6 things from out of a hat and sort of jam them  
7 together, this was -- most of these meta-analyses, not  
8 all of them, but most of them were well conducted,  
9 thoughtfully, and trying to answer the question and  
10 summarize the information."

11 Did I read that correctly?

12 A. I think you did.

13 Q. Thank you.

14 (Pause)

15 Q. Now, Doctor, I think we're well aware of  
16 your criticisms of the meta-analyses on Zoloft, but  
17 you did a mini-meta-analysis, right?

18 A. I did, as I described yesterday, in the  
19 "paused" analysis we had two major studies that  
20 allowed you to independently look at the question of  
21 comparing women on Zoloft and comparing those who  
22 continued to use Zoloft during the first trimester by  
23 some definition versus those who didn't, and I  
24 combined those two in front of the Court yesterday.

25 Q. Right. So there's a couple of steps here,

1 let's see if we can go one at a time. You performed a  
2 calculation or a reanalysis of some of the Huybrechts  
3 data comparing, what you say, women who filled the  
4 prescription in the first trimester and women who did  
5 not fill a prescription in the first trimester, right?

6 A. One or more prescriptions filled, yes.

7 Q. And this analysis or calculation is not part  
8 of the peer-reviewed published study of Huybrechts,  
9 right?

10 A. Well, the data are there in the peer-  
11 reviewed publication, that particular calculation is  
12 not.

13 Q. Right, that was my question. And it's not  
14 part of the investigator's methods, correct?

15 A. I don't know if it's -- the investigator  
16 certainly deliberately tried to separate out these  
17 women that had at least one prescription filled during  
18 pregnancy, because I believe in their sensitivity  
19 analysis they believed that was a more rock-hard  
20 measure of exposure if you actually filled a  
21 prescription. You not only were exposed in that you  
22 had a previous prescription that took you through the  
23 first days after conception, but then you also filled  
24 one. From their sensitivity analysis perception, they  
25 thought that was a more definitive measure of exposure

1 and that's what they used it for. And I used the same  
2 data, but in a slightly different way.

3 Q. Sir, your calculation was not part of the  
4 investigator's methods set forth in the peer-reviewed  
5 published article?

6 A. As I just indicated, yeah, the data was  
7 there in the supplement, but not that particular  
8 calculation, that is new, yes.

9 Q. And in fact Dr. Huybrechts has referred to  
10 reanalysis as a post hoc subgroup analysis, correct?

11 A. As well as referencing it as interesting.

12 Q. And after the fact, post hoc -- I took a  
13 little bit of Latin -- means after the fact, right?

14 A. I actually took a little bit more Latin than  
15 you --

16 Q. There you go.

17 A. -- but I'm surprised you didn't.

18 Q. I rejected it. I looked at it and rejected  
19 it. You haven't published your reanalysis, sir?

20 A. No, I've asked -- as I indicated yesterday,  
21 I believe to take the data from someone else's paper  
22 without approaching that author directly and asking  
23 them to collaborate would be -- not be my scientific  
24 approach. So I have asked the author if she would be  
25 willing to publish them with me, because it's her data

1 and she knows that data, and I think that would be the  
2 right way. And as we discussed yesterday, we're en  
3 route somewhere, I don't know how it will play out in  
4 the end. She may not wish to be involved given how  
5 much contact she's had from lawyers in this case.

6 Q. She politely declined, right?

7 A. No, at the last email she actually indicated  
8 that she would maybe see if some of her team could  
9 help.

10 Q. Let me back up. When you asked her to be a  
11 coauthor, that email politely declined, correct?

12 A. Yes, she said she had too many other  
13 projects. If you want to look at the emails, please  
14 do. And then at the last email, when we had worked  
15 through what I was getting at, she said that's an  
16 interesting possibility or something, and then I'll  
17 see -- I'll bring it up to my team and see if someone  
18 else can. I assume she's too busy.

19 Q. That was your request for the data?

20 A. No, that was the request to publish the data  
21 -- well, that was my request for them to run the  
22 analysis --

23 Q. Right.

24 A. -- adjusting for compounding. I assumed if  
25 they did that they would be willing to stand behind

1       their work and co-publish, but I can't --

2           Q.     That wasn't the question, was it --

3           A.     -- I can't --

4           Q.     -- Doctor?

5           A.     If you could just let me finish. I couldn't  
6       -- I can't speak to that. We're in the middle of  
7       something here. I wrote to Dr. Huybrechts saying  
8       here's an interesting analysis, it's your data, would  
9       you coauthor? She said, I'm too busy, and anyway it  
10      doesn't adjust for compounding. I said, exactly,  
11      that's why I need your help and would you be -- I need  
12      the raw data. She said, I'm too busy, I'll see if my  
13      team can help. Now, whether that leads to a  
14      publication that they want to be associated with or  
15      not, that's for the future to decide.

16          Q.     You have no idea right now, right?

17          A.     Whether it will be done? Well, I can't do  
18      it and I have no control, I think is a better way of  
19      putting it, yeah.

20          Q.     And the data you extracted was from the  
21      supplement of the Huybrechts study, right?

22          A.     That's right, the online supplement.

23          Q.     And you defined some users in that  
24      supplement as "paused"?

25          A.     And I put paused in quotes because --

1 Q. So did I.

2 A. Yes, and so did you, because the word paused  
3 comes from Jimenez-Solem paper and --

4 Q. I'm coming to that, I promise.

5 A. I understand. I --

6 Q. I'm just trying to do this -- right now the  
7 questions are this long and the answers are really  
8 long, Doctor, and I really would appreciate it if you  
9 could focus a little bit more on my question. I will  
10 get there and then your counsel has a chance to do a  
11 redirect.

12 A. I'm sorry, I'm a teacher, I can't help it, I  
13 can't turn it off. That's why I put the word paused  
14 in quotes, it's a slightly different definition than  
15 what's used in Jimenez-Solem --

16 Q. Precisely.

17 A. -- where they use the word paused.

18 Q. So, number one, Dr. Huybrechts did not  
19 define this population as "paused," correct?

20 A. She didn't use that word, that is correct.

21 Q. And, number two, your definition of paused  
22 is different from the Jimenez-Solem definition, right?

23 A. Yes, as I just indicated, yes.

24 Q. And as you said, Dr. Huybrechts pointed out,  
25 you haven't adjusted for compounding, correct?

1           A.    And we discussed that yesterday and the rest  
2   of the story.

3           Q.    Doctor, yesterday there were a couple of  
4   slides, pie charts -- and I'm sorry, I only have  
5   black-and-white, but if I can use the Elmo, maybe  
6   that's easier to see. Okay, let's see if I can --  
7   this pie chart was shown. This is your reanalysis of  
8   the Huybrechts data. And I apologize, that's my  
9   handwriting, "Jewell's definition of paused," we've  
10   already gone through that. And you have an odds ratio  
11   of 1.87, confidence level is 1.07 to 2.39, p value of  
12   0.02, right, that's what you showed us yesterday?

13          A.    Yes, I showed two of these, I believe, and  
14   this is the one, to be precise, that refers to the,  
15   quote, "paused group," I mean, the exposed as filling  
16   one or more prescriptions.

17          Q.    Right. There was another one that talked  
18   about, after Dr. Gibbons commented, you went and did  
19   two or more, right?

20          A.    Correct.

21          Q.    But then we saw another slide, "Meta-  
22   analysis, Huybrechts and Jimenez-Solem." Huybrechts  
23   scored odds ratio 1.9, confidence level of 1.1 to 3.3.

24          A.    Could you show me the previous slide, just  
25   so I can --

1 Q. Yeah.

2 A. -- because that's where I think you're  
3 going. Yeah, that doesn't look right.

4 Q. It doesn't look right, does it, Doctor?

5 A. Yeah, that's -- one of those is --

6 Q. Do we know which one is wrong?

7 A. Well, it will take a minute, because if I  
8 could take logs I could do the symmetry. Maybe Dr.  
9 Kimmel can do it for me, he's better at that with his  
10 eye. I can't tell with -- I think to be fair, I  
11 should correct one of those slides after I've had a  
12 chance to be in a dark room for two minutes.

13 Q. Okay, all right. One of them is wrong, we  
14 don't know which one?

15 A. Yes. The upper bound there looks incorrect  
16 on one of those.

17 Q. Okay. And just so we're clear, based on  
18 your communications with Dr. Huybrechts, you did not  
19 mean your unpublished reanalysis to supersede Dr.  
20 Huybrechts' big published study, right?

21 A. No, and I told her that of course, I didn't  
22 intend that.

23 Q. Right. When you did your meta-analysis, do  
24 you know if you used the correct numbers?

25 A. Which meta-analysis?



1 Q. So you --

2 A. Oh, you mean the two studies?

3 Q. Yeah.

4 A. I would have used the raw data itself, not  
5 the summary results. So I did it myself using the raw  
6 data, not -- so it's a transcription error in one of  
7 those upper bounds.

8 Q. All right.

9 MS. YATES: Your Honor, I am about to  
10 move on and I can hopefully tighten things up. I am  
11 happy to go on or I'm not sure --

12 THE COURT: Well, it is a lunch break  
13 time.

14 MS. YATES: Lunch break? Okay.

15 THE COURT: And I think we should take  
16 the hour again. If that's not enough, let me know,  
17 because we can easily come back at 2:00, but it is  
18 appropriate to break now for our lunch recess.

19 So why don't we get back here in an  
20 hour and assess where we are, and that would be ten  
21 minutes to 2:00.

22 MS. YATES: Thank you, Your Honor.

23 (Proceedings recessed at 12:49 p.m.)

24 \* \* \* \* \*

25

CERTIFICATIONS

I, Sheila G. Orms, certify that the foregoing is a correct transcript from the official electronic sound recording of the proceedings in the above-entitled matter.

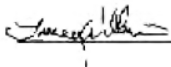
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<b>A</b>	<b>adjusting</b> 42:13 87:19 116:24	96:16 98:10 99:19 101:13 106:24	<b>application</b> 56:11 <b>applied</b> 73:24 96:8 112:24	121:20
<b>AAERT</b> 122:21	<b>adjustment</b> 39:24 40:16	110:18 113:19 114:7,19,24	<b>applies</b> 41:25 <b>applying</b> 51:23	<b>assessing</b> 60:22,25 <b>associated</b> 23:14 25:12 63:20 64:5 64:11,18 65:4 68:23 70:13 117:14
<b>Aarhus</b> 10:15	<b>adjustments</b> 36:25	115:10 116:22 117:8 119:22	<b>appreciate</b> 118:8 <b>approach</b> 3:11 15:16 51:16 72:3 101:15 103:15 115:24	<b>association</b> 21:20 22:4 24:7 60:2 63:10 77:5
<b>AARON</b> 1:19	<b>adverse</b> 113:3	<b>analytic</b> 97:2 <b>analyzed</b> 76:9,21 77:13 101:18,19	<b>approaching</b> 115:22	<b>assume</b> 13:19 14:3 16:19 23:7 39:22 41:24 66:21 68:14 68:15 69:23 116:18
<b>able</b> 58:24 67:13 84:14 96:12 102:14	<b>advised</b> 104:20	<b>anatomically</b> 59:1 <b>ANDREW</b> 1:21 <b>anomalies</b> 24:8 73:6,19	<b>appropriate</b> 66:8 81:1 82:5 90:6,10 91:6 96:4 97:24 98:21 100:14 121:18	<b>assumption</b> 17:9,14 <b>asymmetric</b> 29:18 46:9
<b>above-entitled</b> 122:6	<b>age</b> 55:7 69:18	<b>answer</b> 52:18 80:11 88:18,18 107:21 107:21,23 110:11 111:24 113:9	<b>appropriately</b> 45:6 96:2 100:4	<b>asymmetry</b> 29:7 46:8
<b>absolute</b> 38:20	<b>agency</b> 70:7 83:16	<b>answered</b> 43:18 54:12 76:24 92:8 100:19	<b>approval</b> 16:1,11 16:13,16,21	<b>atrial</b> 23:20,21,23 24:12
<b>absolutely</b> 6:1 12:13 71:5 86:20 102:4	<b>agents</b> 64:17	<b>answers</b> 118:7 <b>antidepressant</b> 78:4	<b>approved</b> 13:20 14:4 15:4,9,24,25 122:11	<b>attached</b> 97:22 <b>attacks</b> 98:18 99:13 99:22 100:22 101:1,9
<b>abstract</b> 51:2,6,9 51:12,17 52:14,20 52:25 53:4,7,10 53:15,18 63:7,18 63:24	<b>ago</b> 37:23,24 38:1 41:17 42:13 74:18 79:19 86:23 109:1	<b>antidepressants</b> 81:20,23 <b>anybody</b> 80:1 <b>anymore</b> 34:10 45:14	<b>arch</b> 24:8 <b>area</b> 6:24 10:21 29:5,6 56:8,9,10 58:2,3,7 82:1	<b>attention</b> 51:25 57:17 62:3 67:7 106:9
<b>abstracts</b> 82:23	<b>agree</b> 4:2 5:23 8:14 11:5 38:17 59:6 60:4,21,24 61:2 62:22 76:19 97:11 104:20,23 106:3	<b>apologize</b> 24:25 30:15 44:25 65:2 71:3 103:18 119:8	<b>arm</b> 112:25 <b>art</b> 20:24 <b>article</b> 37:5,11,19 37:24 40:4 44:6 115:5	<b>August</b> 36:2 <b>Australia</b> 69:9 <b>author</b> 115:22,24 <b>authors</b> 15:12 25:23,24 30:22 32:4 33:10 35:21 36:15 65:11 68:6 68:20 69:12 73:17 79:5,8 84:12 98:15
<b>access</b> 52:12	<b>agreed</b> 27:24 29:7 33:14 81:9	<b>apparently</b> 8:3 50:4 53:9 72:17 81:7	<b>asked</b> 34:7 47:14 47:16,19 53:25 54:1,3,12 67:2 92:4,5,9,16 93:3 100:7 108:23 115:20,24 116:10	<b>author's</b> 83:22 <b>author's</b> 14:8 <b>available</b> 62:4,15
<b>account</b> 71:16 103:2	<b>ah</b> 37:21	<b>APPEARANCES</b> 1:7 <b>appeared</b> 39:5 81:13 82:3	<b>asking</b> 34:6 48:4 87:1 92:22,24 115:22	<b>Avandia</b> 98:1,4,5 98:11,17,19 99:9 99:11,12,18,20 100:2,9,13,24
<b>accounting</b> 102:10	<b>alike</b> 90:3,8	<b>anyway</b> 117:9	<b>assess</b> 61:3 83:22 85:22 97:21	
<b>accumulating</b> 107:18	<b>allowed</b> 54:5 113:20	<b>apologize</b> 24:25 30:15 44:25 65:2 71:3 103:18 119:8		
<b>accurate</b> 52:9,11 74:20 106:1	<b>alphabetical</b> 22:16	<b>apple</b> 108:2,4 109:8 109:9,14,19		
<b>accurately</b> 40:2	<b>alternative</b> 69:15	<b>apples</b> 57:10 108:18,24 109:3,4 109:20,21 111:23 112:22,23		
<b>actual</b> 19:1 43:14 48:2 82:1	<b>altogether</b> 29:21 46:23			
<b>add</b> 75:21	<b>amount</b> 43:2,22 108:10			
<b>added</b> 11:6	<b>analogy</b> 8:24 112:23			
<b>addition</b> 102:9	<b>analyses</b> 62:8,24 77:13 80:14 98:13			
<b>additional</b> 9:6 83:15	<b>analysis</b> 39:1,5 40:5,17,23 41:1 42:4,11 44:3,9,15 52:2,11 62:12 65:19 70:18 71:10 71:16,19 73:1,2 74:11,12 76:12,12 76:25 77:4 85:10 89:15,21 90:8 91:8,10 95:24			
<b>address</b> 35:20				
<b>addressed</b> 34:18				
<b>addressing</b> 61:22 62:18 101:11				
<b>adds</b> 75:17 98:22 100:15				
<b>adjust</b> 37:25 41:14 41:18 73:3 117:10				
<b>adjusted</b> 23:6,8 37:18 38:5 41:15 71:11 73:7 118:25				

101:9,18 102:6,8 102:15 103:5,8,12 103:19,20 104:4 104:20 108:22 110:7,21 111:6 <b>average</b> 108:2 110:14 <b>averages</b> 97:2 <b>averaging</b> 91:4 104:25 105:10,22 106:5 108:1,6,7,9 108:11 110:1,3,17 <b>aware</b> 49:19 50:2 51:1,3 57:5 62:16 62:21 75:23 80:22 113:15 <b>axis</b> 29:6 <b>a.m</b> 1:4,4 66:13,14	<b>believe</b> 3:9 19:17 26:10 29:24 33:10 44:20 49:25 50:5 53:20 54:22 59:23 76:25 92:11 97:18 110:23 114:18 115:21 119:13 <b>believed</b> 25:11 114:19 <b>benefit</b> 26:15 <b>benefits</b> 82:13 <b>Berard</b> 47:9 48:14 49:11,22 51:1,21 52:7,16,19 53:14 53:17 57:1 <b>Berard's</b> 47:14,17 48:24 50:6,11,14 53:4 54:1 57:14 <b>Bernstein</b> 47:12 <b>BERT</b> 1:16,19 <b>best</b> 41:16 53:15 74:2 87:3 <b>better</b> 5:15 12:15 13:1,2,3 16:2 27:24 33:12 100:24 117:18 120:9 <b>beyond</b> 19:24 52:4 <b>biases</b> 61:3 <b>big</b> 21:19 34:20 37:15 67:6 84:5 93:13,15 105:7 120:20 <b>bigger</b> 21:2,3 24:14 35:2 43:10 <b>binder</b> 7:7,11,17 22:15 <b>BIRNBAUM</b> 1:16 <b>birth</b> 13:11 14:10 39:18,23 55:22 56:8,10 58:5,10 62:13,24 77:6 83:20 85:16 90:21 90:23 97:4 99:18 101:4,5 <b>bit</b> 4:1 5:22 7:25 20:20 31:22 42:23	43:1 46:10 49:16 51:9 54:16 55:14 61:15 88:4 93:24 105:16 107:22 111:19 115:13,14 118:9 <b>black</b> 45:12 <b>black-and-white</b> 119:5 <b>blocks</b> 90:4 <b>blurred</b> 63:23 <b>blurry</b> 16:5,7,10 22:6 28:19,19 <b>body</b> 77:4 79:22 84:17 104:4 <b>bore</b> 88:24 <b>born</b> 63:12 <b>bottom</b> 64:24 <b>bound</b> 30:18,19,19 31:5 35:3 38:5,6 38:12 42:14,19 120:15 <b>bounds</b> 38:18 42:22 43:3 121:7 <b>branch</b> 70:8 <b>break</b> 14:23 47:24 48:5 66:21 76:11 121:12,14,18 <b>breakdown</b> 38:24 <b>brief</b> 66:9 83:20 84:10,22 <b>briefly</b> 70:14 75:6 79:9 <b>bring</b> 48:11 88:15 91:9 116:17 <b>bunch</b> 76:1 <b>busy</b> 56:20 116:18 117:9,12	<b>calculation</b> 47:17 48:6 114:2,7,11 115:3,8 <b>calculations</b> 49:5 49:21 50:14 51:24 <b>call</b> 3:3 26:19 <b>called</b> 15:17 63:15 107:3 <b>Callen</b> 4:18,18,19 4:20 5:7 <b>Callen-Reis</b> 8:24 <b>candidate</b> 108:12 <b>can't</b> 94:4 105:18 105:20 106:23 108:25 117:1,3,6 117:17 118:12,13 120:10 <b>capable</b> 107:17 <b>cardiac</b> 21:21 22:4 23:1 26:17 27:8 34:25 35:18 39:21 39:22 62:24 63:11 64:9,11 65:5,14 67:22 70:12 71:12 73:6,10,18 74:3 77:6 80:5 82:19 83:20 85:16 90:21 90:23 96:13,13 97:4 101:4,5 <b>cardiologist</b> 59:4 <b>cardiovascular</b> 55:22 58:22 <b>care</b> 48:13 70:7 82:17 <b>careful</b> 105:21 <b>carried</b> 83:15 <b>case</b> 4:22,22 7:16 27:19 28:2,2,4,5,6 28:11,16 29:19 32:18 33:25 51:10 62:6 68:3 82:24 82:24 84:20 90:16 97:24 98:7 99:9 99:14 101:9 105:17 107:3 108:10 110:21 116:5	<b>cases</b> 28:8 100:3 <b>category</b> 59:24 <b>caught</b> 31:16 <b>causal</b> 112:18 <b>causation</b> 27:11 56:2 60:22,25 92:7 112:15 <b>cause</b> 55:21 <b>causes</b> 56:14 97:3 <b>Celexa</b> 63:19 <b>center</b> 46:1 <b>certain</b> 15:11 62:13 <b>certainly</b> 5:24 7:15 13:13 19:19 26:10 31:1,14 34:4 48:25 56:4,9 63:1 73:14 97:3 99:1 104:2,3 107:23 114:16 <b>CERTIFICATI...</b> 122:1 <b>Certified</b> 122:21 <b>certify</b> 122:3 <b>CET</b> 122:21 <b>chair</b> 28:11 98:1 <b>chance</b> 3:7 34:18 118:10 120:12 <b>change</b> 27:24 30:14 31:6,21,22 35:2,4 35:11,11,12,13 37:20,24 38:2,12 38:19,23 41:22,24 42:14,22,25 43:9 44:8,10,12,12 47:8 51:9 52:17 109:20 <b>changed</b> 30:19 35:5 35:14 38:4 40:16 45:10 49:4 <b>changes</b> 52:15,21 <b>changing</b> 31:2,9 42:23 43:13 <b>characteristics</b> 72:9,10 <b>chart</b> 7:1 14:21 20:12 119:7 <b>charts</b> 119:4
<hr/>				
<b>B</b>				
<b>B</b> 42:5 44:6 <b>back</b> 7:3 10:7,20 14:7 31:15 37:23 38:4 39:9 41:15 43:20 53:11 56:19 56:21 66:10 71:1 82:6 83:8 88:16 93:7,8,8 95:17 98:9 103:6 104:19 110:20 116:10 121:17,19 <b>badly</b> 81:9,11 <b>band</b> 33:20 <b>bar</b> 11:20 <b>based</b> 39:11,11 40:23 46:6 49:5 77:24 105:13 106:3 120:17 <b>basically</b> 40:3 <b>bathroom</b> 67:2 <b>bear</b> 107:22 <b>began</b> 76:12 <b>beginning</b> 53:11 80:12 <b>behalf</b> 56:13 <b>belabor</b> 104:18 <b>belief</b> 112:17				
<hr/>				
			<b>C</b>	
			<b>C</b> 3:1 44:6 <b>CALCAGNIE</b> 1:10 1:11 <b>calculate</b> 47:19 48:14 <b>calculated</b> 47:25 <b>calculating</b> 49:12	

<b>chase</b> 48:22	<b>collected</b> 112:12	<b>concepts</b> 47:3	<b>consider</b> 4:4,21	9:9,10,20 10:3,23
<b>CHD</b> 65:17	<b>Collin</b> 5:10,11	<b>concern</b> 98:23	62:17	11:7,8,16,18,21
<b>check</b> 7:6,9 8:5,9	<b>column</b> 88:24 89:3	100:16	<b>considerable</b> 99:7	11:24 12:2 13:7
8:11 19:5 47:16	<b>combine</b> 98:21	<b>conclude</b> 65:11	<b>considered</b> 69:16	13:10 15:2 16:1
51:15 57:19	100:14 101:13	69:14 84:3 96:12	80:14	16:18,19,22,23
<b>checked</b> 52:3 53:20	109:23	97:3	<b>consistency</b> 27:1	18:8 19:16,21
<b>checking</b> 8:12	<b>combined</b> 113:24	<b>concluded</b> 25:8	60:24	20:1,5,7 21:7,8,11
12:12 49:23 52:5	<b>combining</b> 110:8	73:17	<b>consisting</b> 83:21	21:14,21 22:5
<b>Cheffo</b> 1:15 50:6	112:2	<b>concluding</b> 56:2	<b>consulting</b> 57:2	23:1,19,22 24:5,8
<b>cherry</b> 90:15	<b>come</b> 50:18 63:5	<b>conclusion</b> 69:22	<b>contact</b> 116:5	24:10,13,15,16,19
<b>child-bearing</b>	66:10 71:1 97:5,9	69:23 73:25	<b>contacted</b> 57:8,18	24:24 25:10 27:20
69:18	97:10 106:14	<b>conclusions</b> 25:6	91:25 92:3	30:5,6,7 31:8,13
<b>choice</b> 44:13,13	121:17	<b>conditions</b> 59:5	<b>contacting</b> 91:25	32:16,22 33:3,5
76:3	<b>comes</b> 118:3	<b>conduct</b> 82:13	<b>contained</b> 4:10	35:4,16,19,24
<b>choose</b> 62:20	<b>coming</b> 61:4 97:15	<b>conducted</b> 113:8	31:6	36:18,23 37:6
<b>Citalopram</b> 64:4	110:4 118:4	<b>confess</b> 46:7	<b>CONTD</b> 66:16	39:15,16 40:10
69:16 78:22	<b>comment</b> 79:3 87:6	<b>confidence</b> 23:15	<b>context</b> 4:5 35:2	41:2,3,7 44:7 45:9
<b>cited</b> 58:19	93:19	23:25 24:8,21	79:21 98:25	45:20,23,24 46:19
<b>claim</b> 58:21,24 86:7	<b>commented</b> 76:17	30:9,14,16,18	100:20,21 101:6,6	47:18 48:1 50:12
<b>claimed</b> 42:12	119:18	31:5 33:19,23	101:12,16 102:14	50:13,17,22 53:21
54:14 73:20 81:20	<b>Committee</b> 1:9	35:3,24 36:16	103:3 111:20	54:18 55:22,23
<b>claims</b> 49:11 54:13	<b>communicating</b>	37:1,17,19 38:5	<b>contexts</b> 102:20	56:5,15 57:15
<b>clean</b> 42:6	44:18	38:12 41:9,12	<b>contextual</b> 80:11	58:13,18 59:2,8
<b>clear</b> 27:10 36:11	<b>communication</b>	42:14,18,19,22	<b>continue</b> 63:17	61:5,6,8,19,25
79:2 89:14 97:15	92:18,25	43:3,9 45:22 46:9	<b>continued</b> 113:22	62:1,4 63:21 64:6
99:10 100:1	<b>communications</b>	49:9,13 67:16	<b>contradictory</b> 81:7	64:12,14,15,18
106:10,22 120:17	92:21 120:18	73:7,11 74:8,14	<b>contribute</b> 55:21	65:7,10,14 66:23
<b>clearly</b> 36:15,16	<b>community</b> 56:1,5	119:11,23	<b>control</b> 61:9 81:19	67:17,18,20,21,23
86:3 93:9 104:16	<b>Company</b> 1:23	<b>confidential</b> 24:15	81:22 117:18	69:10,22 70:10
106:17	<b>compared</b> 74:4	<b>confinder</b> 25:12	<b>controlled</b> 103:21	72:19 73:19,20
<b>CLERK</b> 3:2	82:16	<b>confirm</b> 7:20 19:2	<b>conundrum</b> 59:10	74:6,8,9,11,12,14
<b>clinical</b> 98:11 99:1	<b>comparing</b> 14:19	54:2,3,8,13 92:14	<b>conversation</b> 4:2	74:15,21 75:8,10
99:3 100:21,25	25:20 85:25	92:17	<b>copies</b> 66:10	78:15 79:14,15,15
101:7 102:16,23	113:21,21 114:3	<b>confirmed</b> 4:13	<b>copy</b> 22:11,22	80:18 83:4,24
104:5,10,13 112:2	<b>comparison</b> 25:19	48:5 50:9 54:14	65:25 66:6 67:13	89:16,20,22 93:16
<b>clinically</b> 59:1	<b>compatible</b> 33:22	<b>confirming</b> 92:25	87:16 94:1 107:8	93:22 94:21,22
<b>clipping</b> 73:15	<b>complete</b> 5:7 9:8	<b>confounders</b> 37:10	<b>Cornum</b> 5:19 6:2,6	95:8 96:1,13,24
<b>clips</b> 45:17	21:7,10 77:1	<b>confounding</b> 25:21	6:8,10,16,19 7:7,9	98:1,6,24 101:21
<b>close</b> 104:12	<b>completely</b> 4:23	36:25 41:21,25	7:20 8:15,17 9:3,5	104:12 105:12,19
<b>closer</b> 6:23,24	19:3 40:12 55:15	42:24,25 44:11,13	9:11,19 10:2,10	107:20 114:14
44:25	<b>complicated</b> 5:12	44:14 61:4 73:4	11:25 13:22,24	115:10 116:11
<b>coauthor</b> 116:11	50:15	<b>confusion</b> 80:20	14:8,19 17:5,25	118:19,20,25
117:9	<b>compounding</b> 99:5	<b>congenital</b> 56:14	18:9 19:20 21:9	119:20 120:11,24
<b>coauthors</b> 80:25	99:6 116:24	58:1 63:20 64:5	<b>CORR</b> 1:14	122:4
<b>coincide</b> 50:13,16	117:10 118:25	<b>connected</b> 56:24	<b>correct</b> 4:4,21 5:9	<b>corrected</b> 30:4
50:20 52:22	<b>compressed</b> 29:6	<b>connecting</b> 40:21	5:20,21,25 6:7,17	46:13 103:8
<b>collaborate</b> 115:23	<b>conception</b> 114:23	<b>conotruncal</b> 24:7	6:19 8:8,17,22,24	<b>correcting</b> 36:22

42:8 44:8 <b>correction</b> 30:2,2 30:14 32:12,25 33:1 35:21 36:9 36:14 81:11,13 <b>corrections</b> 26:2 <b>correctly</b> 36:19,20 50:24 52:11 63:13 64:7 69:18 71:13 71:14 74:5,9 77:11,15,16 78:7 78:9 83:1,2,23 91:11,12 100:19 108:14,15 110:13 113:11 <b>correspond</b> 40:4 41:14 44:11 <b>corresponded</b> 42:12 <b>corresponding</b> 30:22 <b>corresponds</b> 74:19 <b>couldn't</b> 91:7 98:2 109:21 117:5 <b>could've</b> 15:5,11 <b>counsel</b> 1:9,16 81:8 92:9,12,14,18,20 92:25 118:10 <b>counted</b> 94:23 95:2 <b>counties</b> 6:3,16 10:3,5,11,13,17 10:18 11:6,9 13:8 18:10 <b>counting</b> 95:12,13 <b>countries</b> 21:4 <b>country</b> 6:15 10:9 <b>country's</b> 18:6 <b>county</b> 10:15,22 11:2,2,18,22 14:15 15:1 17:6 17:11 21:15 <b>couple</b> 113:25 119:3 <b>course</b> 11:19 45:17 71:22 75:19 77:2 90:3 97:19 100:4 111:24 120:21	<b>court</b> 1:1,23 3:3,4,6 3:10,13,17 5:3 7:13,15 12:22 13:1 22:18 26:15 28:16 40:6 44:15 45:1,3 48:13,18 58:25 64:22 65:24 66:8,15 79:20,24 87:14,15,19,23,25 94:5,9,14 95:19 98:20 100:12 103:16 104:20 107:9 109:2 113:24 121:12,15 <b>cover</b> 8:2 14:20 <b>covered</b> 8:17 10:14 10:15,16,19 46:15 101:24 <b>covers</b> 6:19 <b>Co-Lead</b> 1:9 <b>co-publish</b> 117:1 <b>crazy</b> 32:5,6 <b>criteria</b> 80:21 81:1 81:21 82:1 107:18 112:8 <b>critical</b> 93:9 <b>criticism</b> 93:10 <b>criticisms</b> 113:16 <b>cross</b> 2:2 66:22 <b>cross-examination</b> 3:19,21 66:16 <b>crucial</b> 43:12 60:22 <b>crude</b> 47:25 49:4 49:21 51:4 <b>cup</b> 42:17 <b>current</b> 99:14 <b>cut</b> 48:22 <b>CYNTHIA</b> 1:6  <hr/> <b>D</b> <b>D</b> 2:1 3:1 42:5 44:6 <b>Danish</b> 5:19 21:5,7 46:21 <b>dark</b> 120:12 <b>data</b> 8:23 9:19 14:14,18 15:12,15 17:15,19 21:7	27:13 33:22 34:1 35:5,10 37:8,9 39:10 40:23 42:20 42:23 43:16 44:4 46:6 49:5 50:22 50:23 52:9,10,12 52:12 54:1,1,4,6,6 54:7,11 59:16 60:17 73:24 75:22 76:9,21 77:2,13 82:21 89:10 97:7 97:21 107:19,24 113:2 114:3,10 115:2,6,21,25 116:1,19,20 117:8 117:12,20 119:8 121:4,6 <b>date</b> 9:12 16:10,13 16:16,17,21,24 17:2 <b>dated</b> 39:2 122:7 <b>dates</b> 6:22 57:17,22 <b>DAUBERT</b> 1:6 <b>DAWN</b> 122:15 <b>day</b> 30:12 92:2 <b>days</b> 114:23 <b>deal</b> 37:15 49:24 50:23 89:25 90:6 91:14 <b>dealing</b> 44:16 59:11 102:15,16 <b>dealt</b> 90:1 <b>debate</b> 32:13 33:9 33:14,16 48:25 49:3,18 50:1 69:2 <b>decide</b> 117:15 <b>declined</b> 116:6,11 <b>DEE</b> 52:21 <b>deeper</b> 97:4 <b>defect</b> 14:10 22:4 23:1 39:19,21,23 42:3 90:23 <b>defects</b> 23:22 24:12 46:17 55:22 56:8 56:10,15 58:1,5 58:11,25 59:8 60:5 62:13,25	77:6 80:5 83:21 85:17 90:21 96:13 97:4 99:18 101:4 101:5 <b>Defendants</b> 1:15 <b>define</b> 118:19 <b>defined</b> 117:23 <b>definitely</b> 22:1 <b>definition</b> 113:23 118:14,21,22 119:9 <b>definitive</b> 59:18 97:6 114:25 <b>degree</b> 39:19,21 54:20 <b>deliberately</b> 114:16 <b>Denmark</b> 5:14 8:18 10:3 13:21 14:4 15:4,25 16:14,25 17:2 19:24,24 20:25 46:18 <b>department</b> 69:13 70:8 <b>departments</b> 69:7 <b>depending</b> 10:14 <b>depends</b> 4:5 48:3 48:18 72:2 <b>deposed</b> 28:7 <b>deposition</b> 27:23 29:5 56:4 81:4 107:1,2 <b>depositions</b> 107:6 <b>depression</b> 82:15 <b>describe</b> 55:9,17 82:8 83:3 84:14 85:7 <b>described</b> 4:25 13:24 24:21 25:18 37:11 38:1 39:16 39:17,18,24 40:2 56:22 59:9 85:15 113:18 <b>describes</b> 38:2 <b>describing</b> 29:17 36:24 <b>description</b> 14:8 31:17 40:3,5,8	41:6,19,21 42:9 44:7,8 50:21 60:20 <b>descriptions</b> 36:22 <b>descriptive</b> 37:3 <b>designed</b> 99:12,19 104:22 112:8 <b>detail</b> 10:8 25:14 32:1 84:14 106:21 <b>details</b> 59:5 107:5 108:25 <b>detected</b> 37:12 <b>detection</b> 100:22 <b>determine</b> 15:10 60:1 63:9 72:6 <b>determined</b> 60:3,7 <b>determines</b> 59:13 <b>developmental</b> 59:1 <b>diabetic</b> 99:21 <b>diabetics</b> 113:1 <b>DIANNE</b> 1:8 <b>didn't</b> 81:7 92:15 95:14 100:12 103:7 104:8,14 113:23 115:17 118:20 120:21 <b>differed</b> 42:20 <b>difference</b> 28:9 34:12 52:24 53:10 53:14 85:25 86:4 86:5 88:19 102:14 109:11,14,17 <b>different</b> 4:14,14 10:13 14:1 15:16 21:4 27:16,20 37:10,14 38:11 39:22 44:14 47:3 72:10 99:24 101:6 101:16 102:13,24 105:1,5 109:4,10 109:13 110:10 112:10,13,16,23 115:2 118:14,22 <b>differently</b> 89:10 102:5 105:3 <b>DIRECT</b> 2:2
---	---	---	--	---



<b>directly</b> 25:20,21 115:22 <b>disagree</b> 25:15,17 25:23,24 69:25 70:1 73:21,22,23 75:11,17 76:19 <b>discovered</b> 39:4,8 <b>discovery</b> 46:3 <b>discrepancy</b> 49:20 <b>discuss</b> 29:10 32:1 49:17 61:22 <b>discussed</b> 4:11 27:23 29:4 34:2 38:8 46:22,22 49:8 59:12 61:24 62:5,9 75:16 76:11,18 80:7,19 81:5,16 83:7 86:21 88:8 102:11 116:2 119:1 <b>discussing</b> 4:6 93:9 99:15 104:15 <b>discussion</b> 31:1 43:6 108:25 <b>dispute</b> 49:9 <b>distinct</b> 109:21 <b>distinction</b> 33:10 33:15 95:16 <b>distinctions</b> 100:1 <b>distort</b> 29:2 <b>distorted</b> 110:5 <b>distorts</b> 29:13 <b>DISTRICT</b> 1:1,1 <b>divide</b> 6:23,25 <b>doctor</b> 3:25 4:16,19 5:6,13,19 6:23 8:11 9:12 10:20 12:8 13:5 14:1,13 16:17 18:3,19 21:16 22:9 23:9 23:18 25:4 26:1 29:1 30:2,12 34:6 36:10 38:14 40:19 46:11 47:2,8 48:20 51:1,19 52:18 53:1 54:17 55:16 56:6,7	57:10 60:4,21 61:15 63:25 65:2 65:20 66:7 67:11 67:14 68:21 69:1 70:15 73:1,13 76:7,19 77:7 79:10 80:16 82:6 86:13,24 88:9 89:13,23 93:21 94:12 95:22 97:11 97:25 100:6 101:3 103:4 106:3 107:15 108:17 110:23 111:6 113:15 117:4 118:8 119:3 120:4 <b>doctors</b> 68:8,12,16 69:6 <b>document</b> 15:17,23 <b>documents</b> 56:3 76:14 <b>doesn't</b> 81:23,24 102:24 117:10 120:3,4 <b>doing</b> 49:21 71:19 72:12 108:3,5,12 109:25 <b>don't</b> 81:12 83:5 84:5 85:7,8,14 87:24 93:4,5 100:23 105:6,10 107:5 110:18 112:4 114:15 116:3 120:14 121:19 <b>dot</b> 78:14,14,14,17 78:17,17,20,20,20 78:21,21,21 <b>doubling</b> 97:15 <b>Dr</b> 3:10,14,18,23 7:12 24:6 31:15 46:2 47:14,17 48:13,24 49:6,10 49:22 50:6,11,14 51:1,21 52:7,16 52:19 53:4,14,17 53:25 54:1,6,24	57:1,14 66:18 74:23 80:24 115:9 117:7 118:18,24 119:18 120:8,18 120:19 <b>driven</b> 105:15 <b>drugs</b> 64:25 112:24 <b>due</b> 25:11 83:19 <hr/> <b>E</b> <hr/> <b>E</b> 1:21 2:1 3:1,1 <b>earlier</b> 4:12 46:16 46:22 76:15 102:21 <b>early</b> 72:22 <b>earth</b> 84:2 <b>ease</b> 27:6 <b>easier</b> 22:22 119:6 <b>easily</b> 38:6,16 121:17 <b>EASTERN</b> 1:1 <b>editor</b> 32:6 <b>effect</b> 99:20 <b>effective</b> 108:12 <b>effectively</b> 34:2 <b>efficacy</b> 99:20 112:9 <b>efforts</b> 73:9 <b>egotistical</b> 55:14 <b>eight</b> 19:16 <b>either</b> 9:19 26:5 35:22 52:7 55:4 93:16 <b>electively</b> 78:4 <b>electronic</b> 122:5,21 <b>electronics</b> 3:7 <b>Eli</b> 62:6 76:14,25 <b>eligibility</b> 112:8 <b>Elmo</b> 119:5 <b>else's</b> 115:21 <b>email</b> 116:7,11,14 <b>emails</b> 81:8,10 116:13 <b>EMANUEL</b> 1:17 <b>emphasis</b> 31:2,6,9 31:22 43:2,4,6 <b>emphasize</b> 31:18	<b>en</b> 116:2 <b>ended</b> 90:17 <b>England</b> 30:21 32:2,12,20,24 36:9 37:1 39:6,13 40:1,9 42:13,21 45:16 <b>enlarge</b> 22:2 <b>entire</b> 6:15 10:9,19 11:14,25 12:3 14:21 17:12 18:6 18:22 33:21 34:20 77:4 93:21 94:18 94:20 95:6 <b>entirely</b> 4:10 26:11 80:12 <b>envelope</b> 92:16 <b>equal</b> 99:4 110:2 <b>equally</b> 78:22 106:13 <b>equation</b> 51:16 <b>equivalent</b> 29:9 101:1 <b>equivocal</b> 97:12,18 97:20 <b>error</b> 26:12 37:3,12 41:20 121:6 <b>especially</b> 61:4 <b>ESQ</b> 1:8,10,12,13 1:14,15,16,16,17 1:18,19,19,21,21 <b>essential</b> 81:25 <b>essentially</b> 113:2 <b>estimate</b> 43:14 73:5 73:11 <b>estimates</b> 35:23 36:16 41:8 59:18 <b>estimating</b> 51:16 <b>ethically</b> 61:13 <b>evaluate</b> 82:13 84:23 <b>evaluation</b> 82:18 82:25 <b>events</b> 113:3 <b>everybody</b> 77:8 <b>everyone's</b> 45:4 <b>evidence</b> 61:4 74:2	77:5 79:22 87:3 97:20 <b>exact</b> 31:3,15 43:11 <b>exactly</b> 23:11 37:18 72:14,15 98:2 102:19 108:15 109:23,24,25 112:7 117:10 <b>examination</b> 44:3 66:23 <b>examined</b> 70:11 <b>example</b> 76:16 84:16 105:4 108:21 <b>exception</b> 21:10 <b>exceptions</b> 113:1 <b>excluded</b> 75:16 82:25 83:19 <b>excluding</b> 81:18 <b>exclusion</b> 81:17 <b>exhibit</b> 29:24 <b>existing</b> 77:23 78:1 <b>expect</b> 52:17 84:15 <b>experience</b> 47:13 <b>experiences</b> 110:6 <b>expert</b> 27:16,18 56:13 57:13 58:21 59:4 <b>expertise</b> 58:24 <b>experts</b> 59:15,16 <b>explain</b> 70:3 72:7 <b>explanation</b> 75:14 <b>explicit</b> 49:23 85:10 <b>explicitly</b> 32:3,4 <b>exposed</b> 14:6,11 15:5,10 16:18 17:7 19:15 81:19 81:23 114:21 119:15 <b>exposure</b> 76:9,22 77:14 114:20,25 <b>extent</b> 60:17 82:2 99:7 102:13 <b>extracted</b> 117:20 <b>eye</b> 29:15,17 35:12 120:10 <b>eyes</b> 16:3 46:7
--	---	--	--	---

87:19 <b>e-mail</b> 32:2 36:1,10 36:15 38:2,24 44:16 <b>e-mails</b> 31:14 32:10 32:13 33:1,8	<b>filmy</b> 87:20 <b>final</b> 53:13 67:17 <b>finally</b> 11:7 <b>find</b> 15:5 36:6 59:19 60:9,11 61:20 69:4 79:16 87:9 90:7 107:17 <b>finding</b> 23:1,21 24:12,18,23 27:8 30:3,4,5,24 46:17 48:17 74:7 89:15 <b>findings</b> 21:21 26:17 27:7,8,9 48:23 50:8,19 51:12 52:21 60:10 73:23 77:21,23,24 82:19 102:10 <b>fine</b> 12:9 28:15 34:5 36:12 59:5 64:1 87:1 110:1 <b>finish</b> 102:2 117:5 <b>Finland</b> 19:24 <b>FIRM</b> 1:13 <b>first</b> 4:9 6:3,11 15:5 27:15,19 28:1,16 39:19,21 57:5 64:22 69:15,17 71:9 73:2 78:4,5 79:6 106:16 113:22 114:4,5,23 <b>five</b> 6:24,25 11:18 37:23,24 38:1 41:17 42:13 94:23 <b>fixation</b> 38:9 <b>flaws</b> 79:14 <b>flipped</b> 18:1 <b>Fluoxetine</b> 78:2,3 89:6 93:20,22 <b>focus</b> 12:21 16:2 35:18 76:7 79:13 104:13 118:9 <b>focused</b> 12:19 14:14 62:3,8 76:12,20,25 77:4 77:12 82:18 96:10 96:21 104:9 <b>focusing</b> 79:11	<b>follow</b> 63:22 64:3 <b>followed</b> 6:8,9 63:14 71:25 <b>following</b> 64:20 69:20 76:20 <b>follows</b> 4:8 <b>footing</b> 99:4 <b>footnotes</b> 85:6 <b>forbid</b> 54:23 <b>forced</b> 49:13 <b>foregoing</b> 122:4 <b>forest</b> 26:14,17,20 27:16 28:1,16 29:21 44:19 46:6 46:16 <b>forget</b> 40:14 <b>form</b> 46:21 <b>formal</b> 33:11 104:21 <b>forming</b> 61:24 <b>formula</b> 31:20 <b>formulated</b> 31:19 <b>forth</b> 115:4 <b>fortunate</b> 61:13 103:21 <b>forward</b> 5:16 60:12 <b>Foster</b> 107:3 <b>found</b> 21:19 22:3 23:20 24:6,11,22 42:8 63:18,19 69:5 70:17,18 71:9 <b>four</b> 6:3,16 10:2,5 11:7 13:8 14:15 18:10 73:4,9 90:17,18 91:1 <b>frame</b> 10:22 <b>frank</b> 43:5 65:22 <b>front</b> 22:11,22 28:11 87:12 113:24 <b>Frye</b> 47:11 <b>full</b> 62:11 <b>fully</b> 83:22 <b>fundamental</b> 85:24 86:5 88:19 <b>fundamentally</b>	89:9 <b>further</b> 5:16 29:2 60:12 71:15 73:8 <b>Furu</b> 19:25 20:6,10 20:11,24 21:7,18 21:18 22:3,17 23:20 24:6,11,22 49:16 <b>fuss</b> 37:16 <b>future</b> 117:15	<b>going</b> 14:17,20,24 22:2,9 23:15,25 27:14 29:16 30:12 32:1 38:12 40:7,9 42:6 44:6,17 60:10 69:2 71:1 79:10 80:1 85:9 90:15 95:19 96:11 98:9 102:23 103:6 104:17,25 111:6 112:17 120:3 <b>good</b> 3:4,5,15,16,23 3:24 46:7,14 55:11 66:3 94:8 <b>gotten</b> 54:4 79:24 <b>grade</b> 90:3 91:17 <b>graduate</b> 55:18 <b>graphic</b> 5:18 6:20 <b>graphics</b> 5:14 7:5 <b>great</b> 71:6 87:18 99:22 <b>greater</b> 34:16 106:21 <b>green</b> 7:24 9:23 10:25 <b>group</b> 60:8 81:19 81:22 119:15 <b>GSK</b> 98:10,15 101:15 <b>guess</b> 46:12 51:18 51:19 <b>guys</b> 105:6 <b>gynecology</b> 69:8,13
<b>F</b> <b>F</b> 1:10 22:16 <b>face</b> 15:14 <b>facing</b> 59:10 <b>fact</b> 29:8 31:5,17 38:10,10,20 41:24 43:5 47:24 49:24 53:17 60:1 62:6 65:11 67:24 75:13 79:3 93:9 99:15 112:5 115:9,12,13 <b>factors</b> 72:7 73:4 <b>fair</b> 7:1 60:20 62:2 83:7 84:12 120:10 <b>fairly</b> 40:11 <b>familiar</b> 15:17 16:20 28:17,21,22 85:4 <b>fan</b> 84:5 93:15 <b>far</b> 8:1 49:19 57:5 62:16 80:9,22 84:19 <b>FDA</b> 91:25 92:3,5,8 92:11,13,19 93:1 <b>February</b> 47:11 <b>feel</b> 91:13 92:6 <b>feeling</b> 60:13 <b>felt</b> 31:5 <b>Ferburg</b> 98:17 101:16 <b>fewer</b> 71:19 <b>field</b> 58:21 <b>Fifty</b> 20:16 <b>figure</b> 13:21 14:5 21:25 22:20 65:12 67:11 <b>fill</b> 114:5 <b>filled</b> 18:23 114:3,6 114:17,20,23 <b>filling</b> 25:12 119:15	<b>F</b>	<b>G</b> <b>G</b> 3:1 122:3 <b>gears</b> 61:15 <b>GEE</b> 52:14 53:7,11 53:19 58:10 <b>generalized</b> 51:16 <b>geographic</b> 8:18 <b>getting</b> 47:5 116:15 <b>Gibbons</b> 119:18 <b>give</b> 3:7 110:10 111:19 <b>given</b> 56:3 116:4 <b>gives</b> 32:3 88:22 106:10 <b>glasses</b> 109:18 <b>go</b> 7:1 10:7,10 12:7 12:7,11,25 15:22 20:10,24 21:24 22:13 32:11 37:23 38:13,17 41:4 43:20 44:19 47:9 50:4,10 53:1 57:9 59:13 60:9,15 63:17 69:11 70:15 74:1 78:20 82:6,6 83:25 84:17 90:12 90:12,14,14 93:7 93:20 95:17 103:10,23 104:19 106:21 110:23 111:21 114:1 115:16 121:11 <b>God</b> 54:23 74:25 <b>goes</b> 16:22 20:12,23 33:19 65:21 89:22 90:3 107:21	<b>G</b>	<b>H</b> <b>H</b> 1:19,21 42:5 <b>half</b> 106:18 <b>hand</b> 4:11 90:15,16 91:1 109:10,14 <b>hands</b> 19:3 68:17 75:3 <b>handwriting</b> 119:9 <b>hang</b> 33:17 <b>happened</b> 51:17 85:3 106:20 <b>happens</b> 95:23 <b>happy</b> 7:8,24 29:8



29:10 43:24 59:13 70:3 75:5 103:8 121:11 <b>hard</b> 22:11,14,22 38:20 65:25 66:6 66:10 67:13 85:12 87:15,20,21 88:1 94:1 <b>harder</b> 29:15 87:23 <b>harms</b> 82:14 <b>hat</b> 113:6 <b>haven't</b> 85:14 115:19 118:25 <b>head</b> 13:18 18:25 21:23 <b>health</b> 70:7,8 <b>Healthcare</b> 83:16 <b>hear</b> 100:18 <b>heard</b> 58:20 79:9 81:12 112:14 <b>hearing</b> 1:6 47:12 47:24 48:5 57:8 57:11 98:3,19 <b>heart</b> 42:3 56:14 58:1,25 59:8 60:5 98:18 99:13,22 100:22 101:1,8 <b>held</b> 109:10,13 <b>Hello</b> 66:18 <b>help</b> 56:23 116:9 117:11,13 118:12 <b>helpful</b> 61:21 <b>helps</b> 44:1,2 <b>here's</b> 88:22 100:9 117:8 <b>heterogeneity</b> 71:13,17,23,25 72:1,3,6,7 74:10 80:7,9,23 86:1,2 88:20,23,24 89:1 89:7,9,16,22,25 90:1,3,6,19 91:3 91:10,15 95:16,17 95:22,24 105:19 106:4,9,25 108:10 108:18,23 109:9 110:3,19 111:18	<b>heterogeneous</b> 59:2 <b>he's</b> 120:9 <b>Hi</b> 66:19 <b>higher</b> 20:15,19 89:6 <b>highlighted</b> 64:25 <b>highly</b> 58:19 <b>hinge</b> 33:24 <b>history</b> 39:18,20 <b>hoc</b> 115:10,12 <b>hold</b> 45:3 <b>homogeneous</b> 110:13 <b>honestly</b> 113:4 <b>Honor</b> 3:5,9,11,20 5:1 7:10 22:19 44:25 48:17,21 50:3 87:9 88:4 94:3,7 103:15 107:7 121:9,22 <b>HONORABLE</b> 1:6 <b>HOOPER</b> 1:21 <b>hope</b> 109:12 <b>hopefully</b> 121:10 <b>horribly</b> 108:9 <b>hour</b> 121:16,20 <b>hours</b> 92:2 <b>Hubrix</b> 54:6 56:17 <b>Hubrix's</b> 53:25 <b>human</b> 35:12 70:8 <b>hundred</b> 20:16 <b>Huybrechts</b> 92:1 114:2,8 115:9 117:7,21 118:18 118:24 119:8,22 119:22 120:18,20 <b>HYDROCHLO...</b> 1:4 <b>hypothetical</b> 108:21 <hr/> <b>I</b> <hr/> <b>Iceland</b> 19:24 <b>idea</b> 40:11 47:5 66:3 109:8 112:15 117:16 <b>identical</b> 7:12	112:4,6 <b>identified</b> 73:4 <b>identify</b> 73:9 <b>ignored</b> 26:11 102:24 <b>illustrated</b> 38:10 <b>impact</b> 35:8,13 <b>implicate</b> 78:1 <b>important</b> 13:19 14:3 15:3 34:23 35:4 38:7 43:7 59:7 60:4,25 61:3 78:17 112:14 <b>importantly</b> 42:15 <b>impossible</b> 83:22 <b>imprecise</b> 60:11 110:14 <b>improper</b> 105:10 <b>inappropriate</b> 91:14 <b>included</b> 39:5 75:13 77:2,18 83:19 97:7 <b>including</b> 33:9 57:14 61:3 65:9 69:12 75:15 76:16 97:7 <b>inclusion/exclusion</b> 80:20 81:1,21 82:1 85:2 107:18 <b>incomplete</b> 75:25 76:1 <b>inconsistencies</b> 39:4 <b>inconsistency</b> 39:8 106:24 <b>incorporated</b> 77:3 <b>incorrect</b> 35:25 41:21 50:22 106:16,17 120:15 <b>increase</b> 23:14,25 24:20 99:12 <b>increased</b> 43:14 64:11 71:11 72:10 73:18 110:7 <b>increases</b> 96:12 <b>independent</b> 4:13	<b>independently</b> 113:20 <b>indicated</b> 21:3 54:12 55:17 58:6 73:9 76:15 91:12 95:10 104:25 115:6,20 116:7 118:23 <b>indicating</b> 92:19 <b>indication</b> 25:22 <b>indirectly</b> 25:19 <b>indiscernible</b> 47:25 111:2 <b>individual</b> 28:14 63:10 64:17 96:15 96:20 97:5 105:25 <b>individuals</b> 13:24 102:8 <b>inevitably</b> 71:22 <b>infants</b> 63:11 <b>inference</b> 97:21 <b>influence</b> 62:1 105:11,13 <b>influenced</b> 31:18 <b>information</b> 4:9,12 4:13 34:17,22 47:6 85:18,19,23 86:2,2 88:22 98:21 100:14 101:8 103:24 104:10,15 113:10 <b>ingestion</b> 25:9 <b>inhibitors</b> 74:4 <b>initially</b> 76:12,25 <b>insights</b> 75:22 102:11 <b>institutions</b> 68:23 <b>insufficient</b> 40:13 <b>integral</b> 23:25 <b>intend</b> 120:22 <b>intended</b> 27:4 41:18 <b>interest</b> 4:11 59:19 <b>interested</b> 80:4 110:15 <b>interesting</b> 115:11 116:16 117:8	<b>interpret</b> 70:22 102:19 103:2 106:16 <b>interpretation</b> 25:17,25 33:22 106:17 <b>interpreted</b> 26:3 <b>interpreting</b> 105:22 106:9 <b>interrupted</b> 88:20 <b>intersects</b> 70:4 <b>interval</b> 4:15 24:15 24:21 30:9,16 31:6 33:19 35:3 37:17,20 42:18,19 42:22 43:3,9 46:9 73:8,11 74:8 <b>intervals</b> 24:9 35:24 36:17 41:9 41:13 45:22 49:9 49:13 67:16 74:14 <b>investigator</b> 114:15 <b>investigators</b> 77:21 113:3 <b>investigator's</b> 114:14 115:4 <b>involve</b> 96:20 <b>involved</b> 11:9 33:9 57:5 68:4 105:23 116:4 <b>in-between</b> 110:5 <b>irrelevant</b> 42:25 <b>Isn't</b> 94:5 109:2 <b>issue</b> 34:15 49:24 50:24 51:25 80:22 86:11 87:25 89:25 95:25 99:9,12 <b>issued</b> 82:11 <b>issues</b> 112:14 <b>it's</b> 81:14,25 82:3 84:7,10,24 85:13 85:23 86:3,6 87:2 87:5,20,21,23,24 88:1,25 89:7,17 90:25 91:5 94:1 96:6 97:14,18 101:6,12 103:1,18
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104:25 105:15,21 106:8,17,20,21 108:18 109:3 110:1,9,24 111:3 112:3,13,21,23 114:13,15 115:25 117:8 118:14 121:6 <b>I'd</b> 81:25 109:5 <b>I'll</b> 116:16,17 117:12 <b>I'm</b> 80:22 84:5,8,9 84:21 87:1,15 88:3,5,13,17 90:15 91:7,19,24 91:25 92:2,22,24 93:13,15,23,25 94:13 95:4,22,22 96:8,11 97:22 101:10 103:8 104:17 105:20 109:23,25 110:22 111:3,12 115:17 117:9,12 118:4,6 118:12,12 119:4 121:11 <b>I've</b> 81:12,24 88:1 91:24,25 97:23 108:6 115:20 120:11 <b>i-squared</b> 88:25	119:22 <b>joint</b> 56:16 <b>JONATHAN</b> 1:17 <b>JOSEPH</b> 1:12 <b>journal</b> 30:21 31:12 32:2,12,20 32:24 33:4,6,11 34:7 36:9 37:2,11 39:6,9,13 40:1,9 42:14,21 45:16 91:16 <b>JR</b> 1:10,21 <b>Judge</b> 47:12 103:19 104:5 <b>Judge's</b> 100:23 <b>judgment</b> 33:4,6 <b>juice</b> 108:4,4 <b>July</b> 16:1 36:17 37:9,22 39:2,3 40:18 41:1,13 42:11 70:6 82:12 <b>jumps</b> 46:11 <b>jury</b> 28:11 <b>Jutland</b> 10:14,23 11:2 13:12,15	65:21 66:22 67:4 68:3,6,9,9,10,11 77:11 81:7,13,25 87:24 92:2,12 96:10 100:23 105:3 114:15 116:3 120:6,14,24 121:16 <b>knowledge</b> 72:8 <b>known</b> 108:8 <b>knows</b> 116:1	111:19 114:1 119:6 <b>let's</b> 5:13 6:18 7:9 9:11 10:10 14:14 15:8,16,22,24 17:2,15 18:10,18 21:18,24 25:7 26:1,3,4,13 28:1 36:1 38:24 44:19 47:8,9 48:11 50:7 53:1 54:16 59:25 63:5,6,6 65:12 70:2,6 72:13,25 75:6 76:6 77:20 78:17,20 <b>level</b> 10:8 23:19 49:10 59:13,17,20 60:14 72:23 85:24 119:11,23 <b>LEVINE</b> 1:19 <b>LGA</b> 36:17 <b>LIABILITY</b> 1:4 <b>Liaison</b> 1:16 <b>life</b> 108:7 <b>light</b> 73:25 <b>Lilly</b> 62:6 76:14 77:1 <b>limitations</b> 80:17 112:1,20 <b>limiting</b> 73:8 <b>line</b> 7:24 45:18 69:15,17 78:4 79:6 107:16 111:9 111:15,21 <b>linear</b> 28:23,24 29:2,13 <b>list</b> 34:20 41:25 <b>listed</b> 67:14 <b>listen</b> 22:14 <b>listening</b> 79:20 <b>literature</b> 54:9 80:1 82:22 98:14 106:15 <b>litigation</b> 1:4 56:12 57:1 76:7 80:16 98:5 99:23 100:10 100:25 101:2,17	101:24 <b>litigations</b> 102:25 <b>little</b> 4:1,16 5:15,22 6:18,22,23 7:1,25 8:1 10:21 12:11 16:2 20:18,20 22:14 25:13 31:22 39:22 42:15,22 43:1,10,10 44:25 46:10 49:16 51:9 54:16 55:10,14 61:15 68:22 88:3 89:9 93:24 101:8 105:6,15 111:19 115:13,14 118:9 <b>lived</b> 108:6 <b>LLC</b> 1:9 <b>LLP</b> 1:12,20,22 <b>location</b> 67:7 <b>log</b> 27:22,24 29:9 29:11,25 45:19,21 <b>logistic</b> 37:12 <b>logs</b> 120:8 <b>long</b> 7:1 30:12 43:24 95:9 108:8 118:7,8 <b>longer</b> 30:24 31:11 32:21 33:2 52:22 52:22 <b>look</b> 6:18 9:11,15 9:18 10:5,7 15:24 17:2 21:5 22:14 26:13 28:1,17 31:14,15 35:10 45:25 50:7 59:22 59:25 60:13,15,16 63:6,6 65:12 68:5 68:15,19 71:16 72:5,25 77:20 78:17 81:9 83:4 83:13,25 88:4 90:8 91:2,8 93:17 95:5 99:12 103:7 103:23 107:1 109:22 113:20 116:13 120:3,4 <b>looked</b> 10:2 19:24
<b>J</b>	<b>K</b>	<b>L</b>		
<b>J</b> 1:5 42:5 <b>jam</b> 113:6 <b>JAMES</b> 1:21 <b>January</b> 17:3,6 <b>Jewell</b> 2:3 3:10,14 3:18,23 66:18 <b>Jewell's</b> 119:9 <b>Jewell's</b> 7:12 <b>Jimenez</b> 5:19 9:19 18:1,6,13 25:7 <b>Jimenez-Solem</b> 6:9 8:7 9:8,14 17:20 17:22 19:20 21:6 25:7 118:3,15,22	<b>K</b> 44:4 <b>KAYE</b> 1:20 <b>KEVIN</b> 1:10 <b>key</b> 95:16 111:24 <b>Kimmel</b> 46:2 49:6 120:9 <b>kind</b> 26:15 90:19 106:23 <b>kinds</b> 62:13 <b>know</b> 7:11 11:17,22 11:25 13:11,13,15 13:20 14:4,15 15:4,9 16:24 17:6 17:10 18:13 19:6 20:23 23:11 28:5 28:13,20 30:10 38:17 40:2,9,12 40:18,20 48:17,21 51:20,21 53:15 56:1 57:7 64:2,14	116:16,19 <b>L</b> 1:16,16,19 <b>language</b> 31:15 81:10 <b>large</b> 26:16 62:9,10 63:2 80:24 112:25 <b>larger</b> 59:20,24 60:8 84:10 89:1 <b>late</b> 6:22 <b>Latin</b> 115:13,14 <b>launch</b> 16:21,24 17:2 <b>LAW</b> 1:13 <b>lawyer</b> 29:8 47:15 <b>lawyers</b> 66:20 116:5 <b>Lead</b> 1:15 <b>leads</b> 117:13 <b>leave</b> 26:4,6 42:17 <b>lectures</b> 55:10 <b>led</b> 46:2 89:3 <b>left</b> 11:12,13 18:16 18:18 24:23,25 25:1 65:16 67:11 <b>left-hand</b> 10:25 <b>lend</b> 107:25 <b>length</b> 13:5 38:8 49:8 59:12 75:16 99:23 <b>let's</b> 82:6,6 83:4,13 83:25 87:7,13 90:6 93:7,17 95:5 103:10 104:19 106:13 107:1 109:19 110:23		

42:9 53:24 62:24 68:9 76:16 96:9 96:14 97:4,6 98:6 101:20,23 103:5 115:18 <b>looking</b> 18:14 19:23 23:5 34:19 64:24 71:19,24 87:15 98:15 99:17 101:2 <b>looks</b> 6:20 7:4 28:20,22 120:15 <b>lose</b> 28:8 <b>lost</b> 11:1 17:17 39:25 64:19 93:24 <b>lot</b> 23:12 26:1 42:1 75:24 90:14 104:11,11 <b>Louik</b> 26:1,2 30:1,2 30:15 31:15 34:19 45:7,25 46:6,16 46:25 <b>Louis</b> 107:4 <b>love</b> 54:6 <b>low</b> 90:2 91:2 <b>lower</b> 19:11 30:15 30:18,19 35:3 38:6,11,18 42:14 43:3 89:5 <b>LP</b> 1:5 <b>lump</b> 46:20 <b>lunch</b> 121:12,14,18	82:20 <b>manufacturer</b> 62:7 62:10 98:10 <b>MARK</b> 1:10,15 <b>market</b> 1:24 16:22 <b>match</b> 40:8 50:8 51:13 <b>matched</b> 53:18 <b>maternal</b> 76:9,22 77:14 <b>mathematician</b> 30:13 91:7 <b>mathematics</b> 54:17 54:21 55:1,3,7 <b>matter</b> 38:3 84:16 89:11 122:6 <b>McDonagh</b> 61:17 62:23 63:2,4 70:2 70:6 71:15 73:17 76:17 77:18 82:6 82:8,11 83:3,5,12 83:14,16 84:5 85:13,25 86:9,11 86:12,14 88:21,23 93:10,18,25 94:2 94:20 95:6 96:9 97:2,8 107:19 <b>MDL</b> 29:21 57:2,5 57:15 61:23 <b>mean</b> 26:5 28:10 39:22 40:13 51:8 102:24 106:21 119:15 120:19 121:2 <b>meaning</b> 89:3,8 <b>meaningless</b> 33:11 33:15 <b>means</b> 46:14 115:13 <b>meant</b> 24:4 26:6 41:17 <b>measure</b> 99:20 110:15 114:20,25 <b>medical</b> 56:6,6,7 68:1,7,16 <b>medications</b> 69:15 <b>medicine</b> 16:22	30:22 32:13,20 36:9 39:6,13 40:9 58:22 69:7 <b>medicines</b> 63:12 <b>meet</b> 3:23 <b>memory</b> 8:10 10:4 12:6 13:13 20:8,9 21:22 51:10,15 98:8 100:23 103:7 103:9 104:12,14 <b>menstrual</b> 39:25 <b>mention</b> 31:4 <b>mentoring</b> 55:12 <b>met</b> 66:20 <b>meta</b> 62:7,11,23 65:18 77:12 80:13 90:7 96:15 97:1 98:9,12 99:18 101:12 106:23 110:17 119:21 <b>metaphor</b> 109:20 <b>meta-analyses</b> 61:16,18 62:4 76:8,21 77:17 96:10,14,17,19,20 96:24 98:6,14,20 100:8,10,13 101:19,20 102:7 102:18,25 106:5 113:7,16 <b>meta-analysis</b> 62:10,17,20 63:18 65:4,13,21 69:20 70:11,17 71:9 74:22 75:14,19 76:13 77:1 79:11 80:2 82:4 83:15 83:17 84:25 85:5 85:12 86:6 91:1 93:15 98:8,16,17 99:2,23 100:2,3 101:10,23 102:9 104:21,24 105:18 106:14 107:25 108:1,13 110:1,6 110:9,12,12 111:25 112:3	120:23,25 <b>meta-analytic</b> 89:4 <b>method</b> 63:14 <b>methodological</b> 79:14 80:17 83:18 <b>methodology</b> 49:12 59:9,25 60:3 62:18 69:21 73:23 83:22 84:14 90:10 91:1,6 93:10 96:4 96:9 97:24 100:4 101:23 102:10 <b>methods</b> 114:14 115:4 <b>MEYERS</b> 1:21 <b>middle</b> 45:22 111:18 117:6 <b>Mid-Atlantic</b> 1:23 <b>Miles</b> 61:17 62:22 63:1,6,7,9,24 67:11 68:16 69:20 76:16 77:2,18,21 77:24,25 78:8,10 78:20 79:13,17 80:3,10,14,18,21 80:25 82:3,5 84:15 85:1,25 86:3,4,9,10 88:19 88:21 96:9 97:2,8 107:19 <b>million</b> 20:4,13,17 21:19 <b>mind</b> 8:12 26:20 96:1 <b>mine</b> 100:24 <b>mini-meta-analysis</b> 113:17 <b>minute</b> 21:18 25:7 63:25 74:18 79:19 86:23 88:12 120:7 <b>minutes</b> 120:12 121:21 <b>mirror</b> 60:2 <b>misappropriated</b> 100:5 <b>mischaracterizat...</b> 101:22	<b>misheard</b> 26:24 <b>misinterpretation</b> 80:6,8 <b>misinterpreting</b> 40:22 51:23 107:23 <b>mislead</b> 105:23 110:18 <b>misleading</b> 79:20 79:24 80:12 91:22 96:6 106:18,20,22 108:9 <b>misled</b> 80:2 <b>misplaced</b> 43:3,6 <b>missing</b> 39:14 41:5 44:6 <b>misspeak</b> 6:7 <b>misspoke</b> 6:5 <b>misstated</b> 41:7 <b>mistake</b> 48:15 <b>mistakes</b> 26:7 49:1 105:10 <b>mix</b> 108:4 112:12 <b>mixing</b> 57:10 108:18,24 109:3,4 110:4 111:23 112:21,22,23 <b>model</b> 52:21 53:7 53:19 58:12,15 <b>modeling</b> 52:14,23 <b>models</b> 53:12 <b>Moose</b> 63:15 <b>moot</b> 82:3 <b>morning</b> 3:4,5,15 3:16,23,24 66:9 72:23 102:21 <b>move</b> 5:1,13 7:24 9:7 17:15 26:1 44:17 54:16 70:2 70:6 76:6 121:10 <b>moved</b> 34:24 45:13 45:17 71:4 <b>moving</b> 38:7,7 <b>multiple</b> 33:25 49:14,25 50:25 51:25 93:2 110:8 <b>multitask</b> 88:5
--	---	---	--	---

<b>M.D</b> 68:24	<b>notable</b> 113:1	73:7 89:4 90:2	<b>ones</b> 64:24 75:15	<b>O'DONNELL</b> 1:22
<b>N</b>	<b>noted</b> 46:2	106:12,12,15,19	90:2,9	<b>P</b>
<b>N</b> 2:1 3:1	<b>notice</b> 46:4	106:19 110:15	<b>online</b> 117:22	<b>p</b> 1:10 3:1 73:12
<b>name</b> 28:13	<b>number</b> 11:13,14	119:10,23	<b>OpenEpi</b> 50:10,12	119:11
<b>names</b> 65:20 68:6	11:17 13:24 14:9	<b>offering</b> 55:21	50:20,21 51:24	<b>PA</b> 1:5,24
<b>NAST</b> 1:8	19:12,15 20:11	<b>official</b> 122:4	52:22 53:18,24	<b>page</b> 7:14 10:10
<b>NASTLAW</b> 1:9	23:16 31:21 42:1	<b>oh</b> 3:13 17:20 23:8	<b>opening</b> 50:6	12:7,20 15:22
<b>national</b> 1:23 8:19	42:3 48:2 74:17	24:5,24 55:3 57:9	<b>opined</b> 56:14	19:7 21:25,25
<b>necessarily</b> 70:1	103:25 104:3	57:12 64:23 71:2	<b>opinion</b> 25:16	22:18,19 64:8
<b>need</b> 16:2 23:10	118:18,21	88:17 94:19 104:2	27:11,14 33:17	65:23 67:24 69:11
40:15 44:24 57:19	<b>numbers</b> 12:5 19:1	104:7 111:3 121:2	34:12 35:8 61:25	69:14 70:17,18,24
61:15 68:15 75:2	21:23 23:12 40:14	<b>okay</b> 4:24 5:12,13	62:2 80:3 91:21	70:25 71:7 74:2
97:20 111:4	42:2 48:9,14 49:1	6:18 7:18 8:4,7,14	92:7 97:6,9,10	77:7,22 82:7
117:11,11	49:3,23 50:12	9:11,12,22,24	106:6	86:15,23 87:2
<b>needs</b> 12:19 65:24	51:11 53:18 65:17	10:1,2 11:6,11,20	<b>opinions</b> 33:24	94:4,5 107:15
<b>neither</b> 78:3	94:4 120:24	11:25 13:5 14:22	35:6 55:20	110:24 111:9,12
<b>never</b> 86:7	<b>numerous</b> 76:8,21	14:23,24 15:8,22	<b>options</b> 82:14	111:13,18,21
<b>new</b> 4:8,8 8:23	77:12	16:10,15,16,24	<b>orange</b> 108:2,4	<b>pages</b> 46:14
30:21 32:2,12,19	<b>O</b>	17:2,5,10,10,15	109:9,19	<b>PAMELA</b> 1:18
32:23 36:8 37:1	<b>O</b> 3:1	17:24 18:4,11,12	<b>oranges</b> 57:10	<b>paper</b> 6:6,6 7:4
39:5,13 40:1,9,17	<b>oath</b> 3:18	18:19 19:5,7,10	108:19,24 109:3	10:7 27:6 31:23
42:13,21 44:23	<b>objective</b> 63:7,9	19:11,14,15 20:10	111:23 112:22	34:19 35:10 39:17
45:16 47:5 68:10	<b>objectives</b> 82:12	21:5,9,25 22:10	<b>order</b> 6:8 22:16	41:4,18 44:14
68:12 69:10 75:21	99:16	22:21 23:20 24:6	79:5	47:9,17 48:4,16
75:22 82:2 115:8	<b>obligated</b> 101:9	25:2,3 26:13	<b>original</b> 7:4 14:8	48:24 49:6,11
<b>newer</b> 77:3	<b>obscure</b> 91:5	28:15 30:1 35:7	37:11 39:1 42:20	50:7,19 51:5,6,13
<b>news</b> 46:14	<b>observational</b> 61:5	36:1,9 37:20	83:6	51:17 52:3,15,20
<b>nice</b> 3:23 105:8	102:17,22 103:4,7	45:19 46:14 47:1	<b>Orms</b> 122:3	52:25 53:12,13
<b>Nicholas</b> 2:3	103:24 104:1,3,15	47:9 50:9,18	<b>ought</b> 69:10 102:12	54:9 56:17 58:16
<b>Nissan</b> 98:16	112:3,4	51:11 53:1,5,6,22	102:14	58:19 69:24 80:12
101:15	<b>observed</b> 101:5	54:10 55:5,20	<b>outcome</b> 59:12	81:6,17 84:15
<b>non</b> 14:13,17 17:5	<b>obstacle</b> 107:24,24	57:9,23 58:14	101:8	85:16 88:1 90:22
23:20 30:4 82:16	108:3,5	60:16 63:7,17	<b>outcomes</b> 14:10	94:3 115:21 118:3
<b>non-exposure</b> 74:4	<b>obstetrics</b> 69:8,13	64:1,4 65:3,11	101:14	<b>papers</b> 19:1 31:18
<b>non-overlap</b> 11:8	<b>obstructions</b> 24:19	67:8,11 68:5 69:3	<b>outflow</b> 24:18,23	33:10 51:9,23
11:12	24:24	69:6,11 70:6 71:4	<b>outside</b> 56:12 98:15	99:14
<b>non-overlapping</b>	<b>obviously</b> 27:13	72:4,25 73:1,17	<b>overall</b> 27:7 35:6	<b>paragraph</b> 64:20
9:12	44:21 62:19	74:1,22 75:4,17	61:22 82:21	74:18
<b>non-pause</b> 25:20	<b>occur</b> 49:15	77:20,22 78:13,24	<b>overlap</b> 5:24 8:24	<b>Paroxetine</b> 64:17
<b>non-significant</b>	<b>occurs</b> 86:11	79:3 83:13 86:13	10:17 11:10 15:7	64:19,19 65:3
50:9	<b>odd</b> 74:13	87:17,18 88:5	15:8 17:16,18,22	78:2,3 89:8
<b>non-statistically</b>	<b>odds</b> 23:4,6,6,24	89:19 94:16,19	18:9,15,16,17	<b>part</b> 9:23 10:25
24:17,22 30:4	24:4,5,8,14 25:8	95:5 102:3 104:17	47:2,4	38:15 59:9 60:22
<b>North</b> 10:14,23	30:17 33:21 45:21	105:9 109:6 111:8	<b>overlapping</b> 4:1	60:25 61:1,25
11:2 13:11,15	47:20 64:11 65:13	119:6 120:13,17	9:13 14:14,18	62:11,17 63:2
<b>Norway</b> 19:25	67:15,19 71:11	121:14	17:6 47:6	84:1,10 93:10,20
		<b>old</b> 26:17	<b>overlaps</b> 9:15 76:5	

114:7,14 115:3 <b>particular</b> 10:24 34:23 46:8 68:3 70:4 76:3 101:17 112:18,19 114:11 115:7 <b>particularly</b> 61:21 <b>patients</b> 12:1,10 99:21 <b>pattern</b> 98:22 100:15 <b>pause</b> 25:20 36:4,7 82:9 106:2 107:10 113:14 <b>paused</b> 113:19 117:24,25 118:2 118:13,17,19,21 119:9,15 <b>Paxil</b> 89:8,12 <b>pay</b> 106:9 <b>paying</b> 51:24 57:17 67:6 <b>PCCP</b> 28:3 <b>peculiar</b> 112:18 <b>Pedersen</b> 5:19 6:8 6:11,15 8:4,16,18 9:4,7,8,13,19 11:9 14:19 17:15,19,25 18:1,5,10,21 19:8 19:9,19 21:6 <b>Pedersen's</b> 6:6 <b>Pederson</b> 65:16,17 <b>peel</b> 71:23 <b>peer</b> 25:15 53:12 54:9 61:17 62:23 63:3 69:21 72:19 72:23 75:9 79:25 80:2 114:10 <b>peer-reviewed</b> 81:14 114:8 115:4 <b>pending</b> 107:3 <b>PENNSYLVANIA</b> 1:1 <b>people</b> 21:12 49:19 51:22 55:10 68:2 69:13 79:20 83:11 110:18	<b>percent</b> 20:15,16 20:18 23:13,19,24 24:20 73:7,11 89:2,7,8,22 90:12 90:24 91:10 <b>percentage</b> 11:23 <b>perception</b> 114:24 <b>perfectly</b> 29:8,10 79:2 107:16 <b>perform</b> 59:7 60:5 <b>performed</b> 114:1 <b>period</b> 4:12 10:19 39:25 82:16 <b>Periodic</b> 15:18 <b>periods</b> 14:9 <b>periphery</b> 43:7 <b>permits</b> 60:17 <b>persistent</b> 98:22 100:15 <b>personal</b> 58:2,6 <b>perspective</b> 59:6 61:13 75:24 <b>Pfizer</b> 29:8 47:15 56:13 62:16,19 91:20,21,22 92:5 <b>ph</b> 4:18 63:15 98:16,17 <b>pharmacological</b> 82:14,17 <b>phenomena</b> 110:13 110:15 112:15 <b>phenomenon</b> 25:22 <b>Philadelphia</b> 1:5,24 <b>physical</b> 108:5 <b>physically</b> 92:15 <b>Ph.D</b> 54:20,22 68:24 <b>pick</b> 45:4 90:13,15 90:15,16 91:1 <b>picked</b> 90:17 <b>picks</b> 80:1 <b>picture</b> 34:20 <b>pie</b> 119:4,7 <b>piece</b> 9:18 35:10 52:1 <b>pieces</b> 33:25 <b>place</b> 67:6	<b>places</b> 91:19 112:10 112:13 <b>plaintiff</b> 28:14,14 <b>plaintiffs</b> 56:13 57:3,13 <b>Plaintiff's</b> 1:8 <b>plausible</b> 73:15 89:24 90:25 <b>play</b> 99:24 116:3 <b>plays</b> 34:16 <b>please</b> 3:6,14,18,19 44:2 52:18 53:1,3 77:7,9 116:13 <b>plot</b> 26:17,20 27:12 27:13,16 28:1,16 29:21 44:19 46:6 46:16 67:15 <b>plots</b> 26:14 <b>plug</b> 50:11 <b>point</b> 4:14 8:19 14:24 22:8 29:4 34:18 38:3 42:11 43:8 44:16 46:24 47:4 75:20 78:25 84:4 88:14 90:8 92:9 110:16,17 <b>pointed</b> 9:6 20:25 29:1 35:9 37:15 39:8 51:22 81:3 102:20 118:24 <b>pointing</b> 49:23 84:9 <b>points</b> 98:12 <b>polite</b> 56:20 <b>politely</b> 116:6,11 <b>pooled</b> 70:18 71:10 73:5,7,10 <b>Popular</b> 58:16 <b>population</b> 4:14 13:15 17:5 112:6 112:7,19 118:19 <b>populations</b> 4:1 5:25 47:7 112:16 <b>positive</b> 41:23 42:10 60:9 <b>possibility</b> 99:6 116:16 <b>possible</b> 61:14	<b>Possibly</b> 109:15 <b>post</b> 115:10,12 <b>post-doctoral</b> 55:11 <b>post-partum</b> 82:15 <b>potential</b> 61:3 73:4 <b>powerful</b> 91:21 <b>POZNER</b> 1:12 <b>precise</b> 17:24 119:14 <b>precisely</b> 13:17 118:16 <b>precision</b> 59:21 60:14 110:7,16 <b>precursor</b> 51:8 <b>predates</b> 6:6 <b>prefer</b> 19:4 <b>pregnancies</b> 14:9 49:14,25 50:25 <b>pregnancy</b> 51:25 69:17 70:13 76:10 76:23 77:14 78:6 82:15 114:18 <b>pregnant</b> 78:5 <b>prescribed</b> 78:22 <b>prescription</b> 19:12 19:13 114:4,5,17 114:21,22 <b>prescriptions</b> 18:23 25:13 114:6 119:16 <b>presented</b> 81:4 <b>presents</b> 80:10 <b>pretty</b> 43:15 106:6 108:11 <b>previous</b> 114:22 119:24 <b>previously</b> 4:19 <b>prime</b> 108:12 <b>principle</b> 40:13 <b>print</b> 103:18 <b>prior</b> 17:6 <b>priori</b> 60:7 107:17 <b>probably</b> 6:24 15:21 29:23 31:25 32:1 51:17 109:21 <b>problem</b> 67:4 106:4	108:18 <b>problems</b> 83:18 <b>procedure</b> 50:23 <b>proceedings</b> 121:23 122:5 <b>process</b> 38:25 82:22 108:1 <b>processing</b> 104:25 <b>produced</b> 29:9 36:25 40:18 42:11 42:21 <b>PRODUCTS</b> 1:4 <b>professional</b> 103:1 <b>program</b> 55:18 87:20 <b>programming</b> 87:24 <b>project</b> 54:8 <b>projects</b> 116:13 <b>promise</b> 14:20 86:24 118:4 <b>pronounce</b> 5:10 <b>pronounces</b> 5:11 <b>properly</b> 104:23 <b>proposing</b> 35:22 <b>protection</b> 29:5 <b>protective</b> 90:20 <b>protocols</b> 62:11 <b>provide</b> 7:12 26:16 75:21,24 <b>provided</b> 36:17 37:8 39:3 40:6 41:13 76:13 <b>provides</b> 59:16 <b>Prozac</b> 62:3,5,9,12 65:6,7 76:7,10,17 76:22 77:5,8,14 77:20,22 79:1,12 80:8,10,16 82:7 82:10 84:8,18,20 85:19 86:1,4 89:6 89:11 93:16,18,19 93:21 94:21,24 95:17 96:11 101:19 102:6 <b>Prozac-specific</b> 82:19
---	---	--	---	--



<b>PSUR</b> 15:17 <b>psychiatry</b> 69:9,14 <b>publication</b> 50:11 72:24 114:11 117:14 <b>publications</b> 82:23 <b>publish</b> 31:21 58:10 115:25 116:20 <b>published</b> 25:15 32:12 51:7 57:25 58:4,8 61:18 62:23 63:3 69:21 72:18 75:9 79:25 80:2 81:14 98:14 114:8 115:5,19 120:20 <b>PubMed</b> 107:17 <b>pull</b> 5:15 12:24 22:9 44:24 63:25 66:6 67:13 77:8 113:5 <b>pulled</b> 113:2 <b>pulling</b> 65:16 <b>pull-out</b> 16:4,5 <b>purpose</b> 110:11 <b>purposes</b> 110:12 <b>push</b> 26:8 <b>put</b> 12:14 13:23 14:18 27:5 29:11 32:2,9 36:1 41:23 42:17,24 43:2,8 46:23 55:15 63:8 76:24 86:16,18 87:5,7,13 90:4 92:15 96:25 104:8 107:12 117:25 118:13 <b>putting</b> 105:8 117:19 <b>p.m</b> 1:4 121:23	86:6 103:3 <b>question</b> 4:6 9:2 14:1 24:17 30:11 34:3 43:17,18,19 44:1 52:19 54:10 59:11 61:22 62:12 62:18 76:24 80:5 88:15 92:6 94:8 95:20 97:14 100:6 100:11,12,19 101:11 107:16 111:10,22 113:5,9 113:20 114:13 117:2 118:9 <b>questions</b> 84:13 88:13 98:16 118:7 <b>QUINN</b> 1:17 <b>quite</b> 37:25 79:3 98:9 99:24 101:6 109:9 <b>quote</b> 70:18 78:8 78:10 93:23 119:15 <b>quotes</b> 117:25 118:14	89:4 90:2 106:12 106:13,15,19,19 110:16 119:10,23 <b>ratios</b> 67:15 71:11 <b>raw</b> 19:1 49:5 52:12 54:7,11 117:12 121:4,5 <b>reach</b> 73:24 <b>reaches</b> 98:23 100:16 <b>reaction</b> 32:4 <b>read</b> 21:22 22:6 33:8 36:10,12,18 36:20 39:20 43:20 63:13 64:7,22 65:22 69:18 71:13 71:14 74:5,9,18 77:9,15,16 78:7 83:1,2,23 87:5,11 87:20,21 90:22 91:11,12 94:4 99:16 108:14,15 110:20 113:11 <b>reading</b> 16:9 23:5 64:2 77:11 79:19 100:20 <b>readjusted</b> 37:9 <b>real</b> 75:14 <b>really</b> 4:4,21 31:25 34:11 48:13 72:2 81:24 89:24 91:5 113:5 118:7,8 <b>reanalysis</b> 114:2 115:10,19 119:7 120:19 <b>reason</b> 18:5 49:20 84:1 89:10,14,17 89:18,18 112:9 <b>reasonable</b> 8:10 59:14 <b>reasons</b> 38:8 54:5 79:12 89:19 <b>recall</b> 47:11 57:16 98:10 107:5 108:22,25 <b>received</b> 17:12 <b>recess</b> 66:9 121:18	<b>recessed</b> 66:13 121:23 <b>recognize</b> 85:5 <b>recognized</b> 95:25 <b>recollection</b> 103:11 103:25 <b>reconvened</b> 66:13 <b>recording</b> 122:5 <b>RECROSS</b> 2:2 <b>red</b> 90:4 <b>redirect</b> 2:2 118:11 <b>reduce</b> 71:22,25 72:1 <b>reduced</b> 73:6,18 <b>reduces</b> 90:23 <b>reducing</b> 72:3 <b>reduction</b> 85:8 <b>refer</b> 15:19,23 65:24 80:17 96:23 109:8 112:1 <b>reference</b> 27:6 30:23 68:22 88:18 <b>references</b> 85:6 <b>referencing</b> 115:11 <b>referred</b> 81:18 115:9 <b>referring</b> 4:17 5:7 5:9 14:7 18:5 82:11 86:13 <b>refers</b> 119:14 <b>refresh</b> 103:25 <b>refreshes</b> 103:11 <b>regard</b> 15:7 46:25 59:23 80:8 86:5 97:25 99:4 <b>regarding</b> 58:1,4,8 77:5 83:18 <b>regards</b> 100:22 <b>region</b> 1:23 8:18 <b>registry</b> 8:19 18:6 18:14 21:5 <b>regression</b> 37:13 39:1 <b>regretted</b> 40:1 <b>REILLY</b> 1:12 <b>Reis</b> 4:18,20 8:23 <b>Reis-Callen</b> 5:8	<b>reject</b> 61:20 84:1 <b>rejected</b> 61:17,24 102:1 115:18,18 <b>related</b> 76:22 77:13 82:19 <b>relating</b> 76:9 <b>relative</b> 39:19,21 <b>release</b> 92:10 <b>released</b> 92:12 <b>reliable</b> 61:21 79:17,21 <b>relied</b> 97:1 101:18 101:19 <b>rely</b> 34:13 105:24 <b>relying</b> 20:8 87:8 <b>remain</b> 3:17 <b>remained</b> 43:15 <b>remains</b> 56:17 80:21 <b>remember</b> 7:3 8:6 10:8 18:24,25 28:4,12,13 31:16 34:3,6,24 43:17 43:19 47:13 48:2 48:8,9 63:3 98:2 100:6 107:2 <b>remove</b> 30:23 31:4 32:20 71:18 90:11 <b>removed</b> 29:20 85:11 <b>removes</b> 33:1 99:5 <b>removing</b> 31:10 73:2 <b>repeat</b> 56:4 <b>replicate</b> 6:11 <b>replicated</b> 46:18 112:16 <b>replication</b> 46:21 47:2,5 60:21 <b>report</b> 15:18,20,24 21:16 27:16,18 28:17 29:21 39:6 57:2 61:18,23 63:2 64:10 70:5 72:5 76:6,18 77:8 77:20,22 78:11 79:1,11,12,16
--	--	---	--	---

80:17 82:7,11,11 83:4,6,14,15 84:10,18 92:4,10 92:13 93:1,19,23 97:2 100:20 101:24 104:4,9,9 104:14,15 106:15 <b>reported</b> 15:12 25:9 37:1 42:5 49:22 65:13 71:11 <b>reporting</b> 1:23 15:15 42:6,20 43:15 64:9 <b>reports</b> 57:14,18 82:24 <b>represents</b> 11:14 <b>reproduce</b> 85:12,13 <b>request</b> 52:2 116:19,20,21 <b>requires</b> 56:2 <b>reread</b> 44:1 <b>rerun</b> 52:2 <b>research</b> 58:3,7 70:7 78:1 83:17 <b>resolve</b> 106:24 <b>resort</b> 106:23 <b>resorted</b> 88:1 <b>response</b> 36:18 39:2 <b>rest</b> 119:1 <b>restate</b> 30:10 <b>restrooms</b> 67:7 <b>result</b> 31:7,19 45:8 50:11 67:12,17 74:13 85:13 90:20 <b>resulted</b> 71:11 73:5 <b>results</b> 25:6,9,18 27:5 31:18 33:16 34:25 35:23 37:4 37:7,16 39:11 40:24,25 42:8 44:4,5,9,10,11 51:4,23 52:3,15 54:8,13,15 64:9 65:18 67:15 75:12 79:18 80:9 86:21 89:3 90:7 96:16	96:18,22,23 97:1 105:11,24 106:10 121:5 <b>resume</b> 3:14 <b>retrieved</b> 39:2 <b>RETENMAIER</b> 1:5 <b>reuptake</b> 74:4 <b>revealed</b> 32:15 <b>review</b> 25:15 53:13 63:3 72:19,23 73:5 76:8,20 77:12,17 82:13,18 82:21,23 93:19,20 104:7,8 <b>reviewed</b> 54:9 61:18 62:23 69:21 75:9 76:8,21 77:13 79:25 80:2 114:11 <b>reviewing</b> 39:1 84:24 <b>re-analysis</b> 37:8 <b>rid</b> 91:3 <b>ridiculous</b> 91:17 <b>right</b> 3:10,17 5:7,22 6:4,10,20,25 7:2 7:23 8:1,14,16,20 8:21 9:16,21,23 10:10,20 11:9,15 11:17,23 13:5,6 13:19,22 14:13,14 14:16 15:3,16,19 16:12,20 17:8,13 17:16,23 18:3,7 18:17,21 19:11,13 19:18,25 20:12,17 20:21,24 21:24 22:25 23:18 24:2 24:18,25 25:1 26:1,18 27:10,15 27:17,21 28:6,15 28:23 29:3,3,13 29:20,22 30:1,21 31:24 32:8,14,19 35:15 36:13,21 37:3,16 39:6 40:7	40:23 44:22,22 45:8,11,15,19,22 46:4,15 47:2,8,17 48:10 49:2 50:2 50:20 51:7,14,19 52:6,13,14,19,23 53:17,25 54:16 55:8 56:19,25 57:2,6,21,25 58:12 60:19 61:7 62:25 63:5,12,14 64:8,16,21 65:8 65:21,21 66:2,12 67:14 68:2,5,7,12 68:13 69:6,11 70:2,9,15 71:1,17 71:21,24 72:5,21 73:13 74:16,22 75:2,7 76:2,6,10 77:17,22,25 78:12 78:14,22 79:6,9 79:17,23 81:2 82:10 83:25 84:3 84:11,23 85:22 87:3,4,12 88:8 93:7,12,17 94:14 94:15,23 95:7,11 95:15,24 97:12,17 103:22 104:7,17 104:19,23 105:2 106:3 108:19,22 109:9,11,16 110:23 111:19 113:17,25 114:5,9 114:13 115:13 116:2,6,23 117:16 117:16,21,22 118:6,22 119:12 119:17,19 120:3,4 120:13,20,23 121:8 <b>rights</b> 67:16 <b>right-hand</b> 14:18 88:24 <b>Ringkjobing</b> 10:16 <b>rise</b> 3:2 <b>risk</b> 23:14,25 24:20	33:23 35:23 36:16 41:8 43:14 59:11 59:18 62:13 70:12 71:12 72:10,11 73:6,18,18 74:3 90:23 96:13 97:15 98:17 99:13 106:16 112:16 <b>Robinson</b> 1:10,11 28:2 44:20 <b>rock-hard</b> 114:19 <b>role</b> 34:16,18 99:24 <b>room</b> 80:6,8 84:6 120:12 <b>roughly</b> 6:20 <b>rounded</b> 32:15 <b>rounding</b> 32:14 <b>route</b> 116:3 <b>Rufe</b> 1:6 103:19 104:5 <b>run</b> 116:21 <hr/> <b>S</b> <hr/> <b>S</b> 1:17 3:1 <b>safety</b> 15:18 99:17 <b>sample</b> 105:4 <b>sample-size</b> 105:14 <b>sampling</b> 112:7 <b>sat</b> 55:10 98:1 <b>satisfactory</b> 85:15 <b>saw</b> 26:14 33:1 37:12 45:18 119:21 <b>saying</b> 11:1 26:3 32:20 37:20,22 38:25 39:10 41:16 53:11 79:5 80:25 84:21 91:16 96:21 101:11 105:20 109:23,25 110:22 117:7 <b>says</b> 31:10 36:8 48:14 52:19 72:5 78:21 81:17 <b>scale</b> 20:11 27:22 27:25 28:23,24 29:2,9,12,13,25	45:19,21 <b>scheme</b> 105:14,15 <b>SCHOLER</b> 1:20 <b>school</b> 20:24 90:4 91:17 <b>scientific</b> 115:23 <b>scientifically</b> 61:21 79:17 <b>scored</b> 119:23 <b>screen</b> 12:14 24:1 24:16 63:23 86:16 86:18 88:5 107:13 <b>se</b> 73:23 86:6 <b>SEAN</b> 1:13 <b>searches</b> 82:23 <b>searching</b> 12:23 107:17 <b>seated</b> 3:6,18 <b>second</b> 4:7,10 70:22 <b>section</b> 8:21 64:8 83:20 84:1 93:18 93:21 94:18,20 95:6,7 <b>sections</b> 14:23 <b>see</b> 4:2 10:11 17:3 27:7 28:18 38:24 46:8 68:16,23 78:25 87:14 88:23 89:6 91:9 98:21 100:14 103:11,14 104:19 109:5 111:17 114:1 116:8,17,17 117:12 119:6,6 <b>seeing</b> 4:12 101:14 112:15 <b>seen</b> 48:23 56:17 70:16 81:2 <b>select</b> 72:3 <b>selection</b> 82:22 <b>selective</b> 74:3 <b>self-taught</b> 55:8,15 <b>send</b> 81:11 <b>sending</b> 39:9 <b>Seng</b> 98:16 101:16 <b>sense</b> 42:16 59:22
---	---	--	---	--

60:6,6,9 76:13 99:3 108:6 <b>sensitivity</b> 71:19 73:1,2 74:11,12 85:9 86:22 89:14 89:21 91:8,10 95:23 114:18,24 <b>sent</b> 92:4,19 <b>sentence</b> 64:22 70:4 72:25 79:1 <b>sentences</b> 83:21 84:2,3,17,22 86:14 93:11 94:23 95:9 <b>separate</b> 47:6 114:16 <b>septal</b> 23:22,23 24:12 35:15 40:15 42:3 46:17,25 <b>September</b> 1:3 122:7 <b>series</b> 82:24 <b>serious</b> 73:10 <b>Serotonin</b> 74:3 <b>sertraline</b> 1:3 13:6 23:2,24 40:14 64:4,13,13,14 65:9 69:16 71:7 73:6 74:7 78:21 83:20 89:2,15 95:5,7 <b>Services</b> 70:9 <b>SESSION</b> 1:4 <b>set</b> 3:7 4:8,8 18:10 32:25 33:21 37:10 37:10 39:16 40:17 40:23 44:4,11 49:7 66:15 107:17 115:4 <b>sets</b> 38:11 <b>settings</b> 102:6 <b>seven</b> 71:10 84:20 85:6,8 90:12,17 <b>sheet</b> 26:16 27:6 <b>Sheila</b> 1:16 122:3 <b>she's</b> 116:5,18 <b>shift</b> 61:15	<b>shouldn't</b> 102:18 102:21 <b>should've</b> 39:20 <b>show</b> 48:7 50:5 53:3 64:16 72:9 72:11 103:10 119:24 <b>showed</b> 119:12,13 <b>showing</b> 45:7 <b>shown</b> 119:7 <b>shows</b> 106:11,12 <b>side</b> 14:19 18:11 26:8 67:3 <b>signal</b> 59:23 60:8 101:15 <b>Signature</b> 122:11 <b>significance</b> 30:23 32:21 33:2 34:1 34:13,16,22 49:10 98:23 100:17 <b>significant</b> 21:20 22:3,25 23:18,21 24:7,11,18,23 25:8 30:3,5,25 31:7,11,12,19 32:22 33:3,16,18 34:8,9 45:8,13 46:17 48:17,25 50:19 51:13 73:16 79:4 86:3 <b>significantly</b> 63:20 64:5,10,17 65:4 <b>similar</b> 90:18 98:15 99:13 <b>simple</b> 106:14 <b>simply</b> 42:2 90:1 <b>single</b> 27:6 34:1,15 54:9 90:21 <b>single-group</b> 82:24 <b>sir</b> 5:23 8:14 10:5 10:11,22 13:11,21 14:20 31:9 32:11 33:6 42:8 43:19 46:16 53:4,8 62:22 77:15 80:24 91:7 92:13 109:2 115:3,19	<b>sit</b> 76:4 <b>sitting</b> 28:10 <b>situational</b> 102:12 <b>situations</b> 106:23 <b>six</b> 90:12 <b>sizes</b> 105:4 <b>slide</b> 36:14 50:5 119:21,24 <b>slides</b> 36:6 119:4 120:11 <b>slight</b> 35:8 <b>slightly</b> 14:1 37:9 37:14 38:11 46:1 115:2 118:14 <b>slip</b> 42:19 <b>SLONIM</b> 1:19 <b>sloppy</b> 39:25 <b>slower</b> 12:11 <b>smacked</b> 74:25 <b>small</b> 11:22 12:22 99:10,20 100:22 110:8 <b>smaller</b> 43:11 <b>software</b> 50:15 52:2 <b>sole</b> 34:21,22 54:23 89:18 <b>solely</b> 55:3 97:1 <b>Solem</b> 5:20 9:20 18:2 25:8 <b>Solem/Pedersen</b> 18:14 <b>somewhat</b> 82:3,20 97:5 112:10 <b>soon</b> 92:9 <b>sophisticated</b> 49:12 52:1 90:5 105:16 <b>sorry</b> 5:6 8:25 9:17 10:25 12:11 15:25 17:17 21:25 25:2 36:6 50:3 63:22 64:20 70:17,20 71:2 88:13,17 93:24,25 111:3,12 111:13 118:12 119:4 <b>sort</b> 25:11 46:11	113:6 <b>sound</b> 109:7 122:5 <b>sounds</b> 8:9 73:14 <b>source</b> 34:21,22 <b>sources</b> 82:21 <b>SOUTH</b> 122:15 <b>space</b> 85:14 <b>span</b> 27:7 <b>speak</b> 62:19 117:6 <b>SPEAKER</b> 111:1 <b>specific</b> 4:16 9:5 44:11 56:9,10 59:8 60:5 63:14 107:6 <b>specifically</b> 4:17 5:9 49:6 62:8 80:4 81:17 99:15 99:17 <b>specified</b> 37:5 <b>speculate</b> 53:16,23 <b>speculation</b> 38:14 38:16,19 52:24 53:9 <b>spend</b> 104:14 <b>spending</b> 97:19 <b>spent</b> 79:18 84:25 85:9 <b>spin</b> 41:16,23 42:10 <b>spoken</b> 31:23 <b>SSRI</b> 58:9 69:15,17 <b>SSRIs</b> 40:15 63:10 99:17 <b>St</b> 107:3 <b>stand</b> 3:14 40:24 41:8 116:25 <b>standard</b> 31:12 32:17,19,23 33:7 33:11 <b>standing</b> 37:4,7 <b>STARK</b> 1:14,14 <b>start</b> 3:25 4:2 <b>started</b> 56:25 62:6 <b>starting</b> 107:16 <b>starts</b> 20:10 99:24 <b>state</b> 27:18 28:5,16 36:15,16 <b>stated</b> 39:12 82:12	<b>statement</b> 76:20 79:4,5,7,8 99:1 101:12 <b>statements</b> 74:20 81:5,6,6 <b>states</b> 1:1 64:10 <b>stating</b> 31:7 <b>statistic</b> 88:25 <b>statistical</b> 34:1,13 34:16,21 38:20 49:10,12 50:22 59:21 60:14 71:13 72:6 75:22 98:23 100:16 106:17 <b>statistically</b> 21:19 22:3,25 23:17,21 24:6,11 30:3,5,24 31:7,10,11,19 32:21 33:3,16,17 34:8,9 45:8 46:17 48:16,24 50:19 51:13 60:11 86:3 90:5 <b>statistician</b> 33:9 54:14 55:8 58:23 61:12 97:21 102:19 <b>statisticians</b> 33:24 43:1 59:15,17 68:1 108:8 <b>statistics</b> 55:19 102:24 <b>status</b> 63:3 <b>stay</b> 14:14 38:20 43:24 <b>stayed</b> 30:17,19 <b>Steering</b> 1:8 <b>step</b> 6:3,11 59:24 <b>STEPHEN</b> 1:14 <b>steps</b> 113:25 <b>stick</b> 14:21 18:3,18 21:18 <b>story</b> 81:12 119:2 <b>straight</b> 32:11 <b>strange</b> 90:20 <b>Street</b> 1:24 <b>strength</b> 63:10
---	---	---	--	--



112:5,13,21 <b>strengthen</b> 112:17 <b>strike</b> 21:17 <b>stroke</b> 98:18 <b>strong</b> 79:4,7 <b>strongly</b> 91:13 92:6 <b>struggling</b> 88:3 <b>student</b> 90:4 91:17 <b>studied</b> 10:11,13,22 20:4,6 <b>studies</b> 4:17 5:8,19 5:23 7:7,11 9:3 34:20 44:22,23 46:5,19,21 47:6 49:15 54:7 61:5 67:14,25 71:10,20 72:9,11 73:3,9 75:7,8,13,15,20 75:23 76:2 77:2 80:14 81:18,22 82:2,5,24 83:19 84:20 85:4,6,11 90:11,16 91:2 96:15,21,23 97:5 97:7,9,11 99:4 101:13 102:17 103:5,7,24 104:1 104:3,22 105:1,7 106:11,25 108:11 110:8,11 112:3,4 112:24 113:19 121:2 <b>study</b> 4:3,3,4,7,9 4:21 10:6 11:15 12:1,3 13:5,6,25 15:13 17:12 18:21 18:22 19:23 20:12 34:15 46:23 47:14 63:18 65:20 69:12 80:25 82:21 84:13 97:15 101:2 102:22 104:15 105:11 106:18 114:8 117:21 120:20 <b>studying</b> 113:1 <b>study's</b> 83:20	<b>subcategories</b> 14:11 59:22,25 <b>subcategorization</b> 59:14 <b>subcategory</b> 27:9 34:23,25 35:14 60:2 <b>subgroup</b> 59:20 60:10,13 115:10 <b>subgroups</b> 60:15 60:16 <b>subjected</b> 72:18 <b>subjects</b> 47:8 <b>submit</b> 35:22 <b>submitted</b> 57:1 93:1 <b>submitting</b> 35:22 <b>subpoena</b> 36:18 39:2 <b>subsequently</b> 51:4 103:23 <b>subset</b> 4:3,20 5:8 8:15,20 9:3,8 21:10 <b>subsets</b> 19:20 21:7 <b>substantial</b> 105:25 <b>substantially</b> 89:4 105:4 <b>subsumed</b> 4:7,23 <b>sub-analyses</b> 59:7 60:5 <b>succeed</b> 56:18 <b>suffering</b> 83:18 <b>sufficiently</b> 85:4 <b>suggested</b> 73:18 78:2 <b>suggesting</b> 73:5 <b>suggests</b> 90:22 91:20 <b>suing</b> 56:13 <b>Suite</b> 1:24 <b>sum</b> 79:10 102:11 <b>summarize</b> 113:10 <b>summary</b> 96:16,18 96:22 97:1 105:24 121:5 <b>supersede</b> 120:19	<b>supplement</b> 115:7 117:21,22,24 <b>support</b> 27:11 <b>supposed</b> 67:1 110:10 <b>sure</b> 5:17 9:17 10:2 12:16 23:5 30:12 40:8,21 42:7 44:2 47:10 65:15 66:4 70:23 72:23 78:19 86:20 95:4 103:13 104:22 105:9 109:12 121:11 <b>surprise</b> 84:6,7 <b>surprised</b> 115:17 <b>suspect</b> 97:16 <b>swear</b> 57:4 <b>Sweden</b> 5:13 19:25 <b>Swedish</b> 4:17,22 <b>switched</b> 17:20 <b>symbol</b> 23:15 <b>symmetry</b> 120:8 <b>system</b> 87:25 <b>systematic</b> 82:13 <b>systematically</b> 60:1 71:23 90:11 <hr/> <b>T</b> <hr/> <b>tab</b> 53:1 57:9 77:7 <b>table</b> 12:8,18 13:23 19:6 22:19 23:12 40:14 41:19 42:1 42:2 70:15,16,24 71:1,12 74:1,2,19 86:15,20,23 87:1 87:3,4 88:8,22 91:9 93:8 94:6,13 94:19 <b>take</b> 6:18 8:13 9:11 10:20 12:6 15:8 15:14 25:5 26:3,6 28:20 32:9 38:18 53:12 55:18 57:20 63:6 65:12 66:9 90:13 91:23 93:17 103:2 107:1 108:2 108:3 110:13	115:21 120:7,8 121:15 <b>taken</b> 15:11 107:2 <b>takes</b> 14:25 63:25 <b>talk</b> 14:17 25:14 30:1 47:1 59:3 61:16 66:21 67:8 73:1 75:2,5,6 86:14,24,25 <b>talked</b> 26:2 36:23 47:2 66:24,25 103:22 119:17 <b>talking</b> 3:25 10:21 14:13 17:25 23:2 23:11,13,16 25:4 25:6 34:24 84:8,9 84:25 86:9,10 88:21 103:20 <b>TAM</b> 1:17 <b>target</b> 38:7,7 <b>targeted</b> 99:15 <b>tea</b> 42:17 <b>teacher</b> 118:12 <b>team</b> 49:22 56:23 116:8,17 117:13 <b>techniques</b> 104:21 105:9 <b>tell</b> 58:25 68:20 81:25 85:8 88:4 100:12 102:13,14 109:10,14,17 120:10 <b>telling</b> 16:11 52:7 <b>tempest</b> 42:17 <b>ten</b> 46:24 103:6 109:1 121:20 <b>tending</b> 88:5 <b>teratologist</b> 55:24 <b>teratology</b> 56:1 <b>terms</b> 76:4,4 79:18 <b>terribly</b> 108:7 <b>testified</b> 4:19 5:22 28:6 47:22 52:4 97:12,25 99:2,11 105:17 <b>testify</b> 98:3 <b>testifying</b> 47:11	<b>testimony</b> 48:7 66:22,25 67:9 100:7 101:25 102:12 103:11,19 104:4 109:5,24 <b>thank</b> 3:13,14,20 5:4 7:17 12:14 13:3 36:12 66:12 94:19 107:11 111:14,16 113:13 121:22 <b>that's</b> 81:12 83:3,7 84:6,20 86:4 87:1 88:21 89:9,17,24 90:5,19 91:3,14 93:21 94:7,20 95:6 96:1 97:20 97:22,23 99:1,8 99:23 100:18,19 100:21 101:11,16 101:22 104:14 105:8 106:6,7,7 106:16,20 108:15 109:19,23,24,25 110:11,16,17,19 110:20,21,21 111:1 115:1 116:15 117:11,15 117:22 118:13 119:6,8,12 120:2 120:5 121:16 <b>therapy</b> 78:4 <b>there's</b> 80:24 84:2 85:21,23 86:11 89:4,5,8 90:21 93:11 97:14 98:22 101:14 104:24 105:24 108:2,5 110:19 113:25 <b>they're</b> 85:10 87:8 99:17 101:24 104:16 <b>they've</b> 92:23,25 <b>thing</b> 23:5 99:8 111:10,22,24 <b>things</b> 22:14 29:2 70:12 110:2
--	--	--	--	---

112:12,21 113:6 121:10 <b>think</b> 5:6,11,14,18 6:5,6 7:22 12:24 16:7 21:25 23:8 25:13,18,21 26:4 26:7 27:4,18 28:7 29:23 31:3,4 32:23 34:11 35:7 41:16 43:18 46:2 48:3 51:3,3 52:13 55:2,14 60:18 62:2 63:1 64:21 65:24 66:2 67:12 68:10 69:2 70:16 74:17 76:16 79:1 79:19,24 80:4 81:5,11 83:5 84:5 84:24 86:13 88:14 89:24 90:16 91:13 94:9 95:16,19 96:5,6 97:9 112:1 113:4,12,15 116:1 117:18 120:2,10 121:15 <b>thinking</b> 95:22,23 <b>thought</b> 11:1 26:3 26:25 32:5,6 34:2 56:22 106:22 114:25 <b>thoughtfully</b> 113:9 <b>three</b> 5:18 28:8 46:20 73:3 75:6,8 75:13,20,23 76:2 76:3 83:21 84:2,3 84:17,22 86:14 93:11 95:9 102:6 102:7,9 <b>throw</b> 90:9 <b>tighten</b> 121:10 <b>time</b> 4:13,15 10:22 14:9 22:15 43:22 45:7 46:15 66:9 79:19 84:25 85:9 95:17 97:19 108:8 114:1 121:13 <b>timeframe</b> 14:5	15:11 <b>times</b> 28:8 35:17 81:24 93:2 <b>timing</b> 57:7 <b>tiny</b> 103:18 <b>title</b> 50:8 53:3 74:2 <b>today</b> 55:21 82:4 101:17 110:22 <b>told</b> 35:17 49:19 78:16 92:7,16,23 93:2 98:19 109:2 120:21 <b>top</b> 13:17 18:25 21:23 <b>total</b> 11:14 13:9 19:15 20:11 54:23 <b>Trace</b> 107:3 <b>TRACEY</b> 1:13,13 122:20 <b>track</b> 14:25 28:8 69:1 <b>tract</b> 24:19,23 <b>train</b> 11:1 <b>trained</b> 97:23 <b>training</b> 55:11 56:6 <b>Transcriber</b> 122:11,21 <b>transcript</b> 48:12 107:8 110:24,25 111:4,4,7 122:4 <b>transcription</b> 26:11 41:20 121:6 <b>treat</b> 89:10 102:18 102:21,22 <b>treating</b> 99:21 <b>treatment</b> 82:14,18 112:25 <b>treatments</b> 69:17 82:17 <b>tremendous</b> 43:2 <b>trial</b> 29:24 44:20 61:9 92:6,9 102:23 104:10 112:8,9,9,19 <b>trials</b> 98:12,13 99:1 99:3,10,11,18,20 100:21,25 101:7	102:16 103:22 104:6,13 105:25 112:2 <b>tried</b> 6:11 28:3 71:18,18 86:7 97:23 106:10 114:16 <b>TRIGG</b> 1:22 <b>trimester</b> 78:6 113:22 114:4,5 <b>trouble</b> 87:9 <b>true</b> 14:6 99:1 109:2 <b>truth</b> 43:7 52:7 91:5 <b>truthfully</b> 92:8 <b>try</b> 15:16 29:16 54:1 56:22 71:16 72:6 79:10 95:25 <b>trying</b> 22:13 43:22 50:7 56:16 84:4 84:13 91:4 112:12 113:4,5,9 118:6 <b>turn</b> 25:7 46:14 67:24 86:15 101:10 107:15 111:9 118:13 <b>two</b> 4:17 5:8 9:3 18:13,23 19:12 21:12 28:7 47:3 48:23 49:1,3,4 50:18 51:12 52:15 52:21 73:2 86:21 90:13 106:11,12 106:25 109:13,20 113:19,24 118:21 119:13,19 120:12 121:2 <b>two-year</b> 54:8 <b>types</b> 58:5 109:4	<b>underneath</b> 65:18 <b>understand</b> 9:2,7 9:18 26:5,21 78:9 84:19 85:1,18 91:13,22 118:5 <b>understanding</b> 19:22 <b>Understood</b> 96:5 <b>undetectable</b> 35:12 <b>undue</b> 105:11 <b>unequivocal</b> 97:16 <b>unfair</b> 55:10 <b>unfortunate</b> 61:12 <b>unfortunately</b> 61:11 <b>UNIDENTIFIED</b> 111:1 <b>UNITED</b> 1:1 <b>unknown</b> 25:12 <b>unpublished</b> 120:19 <b>Update</b> 15:18 <b>updated</b> 44:21 51:4 83:14 <b>updates</b> 76:4 <b>upper</b> 30:18 33:20 43:2 120:15 121:7 <b>urged</b> 92:5 <b>USA</b> 1:5 <b>use</b> 13:20 14:4 18:6 20:11 29:16 33:7 33:12,13 38:11 50:23 51:15 59:18 62:20 70:13 79:6 79:6 81:10 96:4 100:2,2,8 101:12 102:23 104:9 112:22 113:22 118:17,20 119:5 <b>used/excluded</b> 81:21 <b>useful</b> 98:20 100:13 101:12 107:25 <b>users</b> 13:6 117:23 <b>uses</b> 31:12 52:20 <b>usual</b> 82:17 <b>usually</b> 16:21 51:9	68:22 85:15 105:14 <hr/> <b>V</b> <hr/> <b>valuable</b> 108:7 110:3 <b>value</b> 15:14 43:11 73:12 99:2 103:2 110:5,6 119:11 <b>values</b> 33:21 90:2 91:2 <b>variability</b> 50:24 <b>variable</b> 35:1 39:18 42:24,25 <b>variables</b> 36:23,24 37:5,18,25 38:4 38:11,18,23 39:11 39:12,12,16 40:4 40:5,16,17,23 41:5,13,15,18,21 41:25 42:4,18 43:8 44:12,13,14 <b>variation</b> 105:25 <b>varieties</b> 109:13,21 112:23 <b>various</b> 82:14 98:12 <b>vary</b> 89:4 112:9 <b>ventricular</b> 23:22 23:23 24:12,18,23 <b>verbally</b> 92:23 93:2 <b>Veritext</b> 1:23 <b>version</b> 53:13 <b>versus</b> 113:23 <b>Viborg</b> 10:17 <b>view</b> 75:21 108:13 112:5 <b>viewing</b> 35:4 <b>visualization</b> 26:19 26:22 27:20 28:25 <b>vis-à-vis</b> 57:8 <b>voice</b> 45:4 <hr/> <b>W</b> <hr/> <b>wait</b> 88:12 95:19 <b>waiting</b> 88:15 <b>Wang</b> 74:23 75:2,6
--	--	---	--	--

84:16 <b>want</b> 8:11 9:18 19:5 23:6,8,10 30:10 31:2,20 35:20 37:23 38:1 43:24 59:4 75:5 86:10 87:12 94:1 106:1 108:1 116:13 117:14 <b>wanted</b> 3:25 16:7 27:4,5 30:23 31:4 31:21 37:15 64:2 83:11 88:15 91:9 111:10,22 <b>wasn't</b> 88:15 100:12 117:2 <b>wasn't</b> 34:9 57:17 <b>way</b> 5:15 6:12,14 11:13 13:21 19:18 20:12 27:5 29:16 38:1 39:15,24 40:12 43:13 49:16 52:5 55:17 67:2 72:1,5 84:15 89:25 90:6,7 91:14,19 96:6 98:21 100:14 102:19,22 105:8 107:19,19 115:2 116:2 117:18 <b>ways</b> 98:9 <b>weakness</b> 112:6,11 <b>weight</b> 91:24 105:1 105:7 <b>weighted</b> 104:22 106:13 <b>weighting</b> 105:14 105:23 <b>well-conducted</b> 111:25 <b>went</b> 7:3 26:18 30:16 57:14 69:1 89:13 93:8 99:22 119:18 <b>weren't</b> 67:1 <b>we're</b> 87:9 88:21 95:19 103:6 111:6	113:15 116:2 117:6 120:17 <b>we've</b> 84:25 99:14 119:9 <b>we'll</b> 63:5,8 66:9 <b>we're</b> 5:7,9 7:13 22:9 23:5 25:4,6 31:25 40:21 47:5 57:9 71:1 <b>we've</b> 8:20 17:20 18:1 20:20 34:24 38:8 46:15 48:23 70:16 75:16 <b>what's</b> 96:1 118:15 <b>WHEELER</b> 1:22 <b>wider</b> 24:15 <b>WILLIAMS</b> 122:20 <b>willing</b> 92:10 115:25 116:25 <b>wine</b> 109:17 <b>wish</b> 36:15 41:13 80:15 92:1 116:4 <b>wishing</b> 78:5 <b>witness</b> 2:2 3:16 7:13,18 12:25 13:2 22:21 28:11 64:23 66:1,4,12 87:11,18 88:2,6 94:16 98:1 107:11 <b>WOLFF</b> 1:16 <b>woman</b> 15:13 <b>women</b> 4:8 11:14 13:21 14:6,11 15:5,10 16:17 17:7 18:23 19:16 20:4,12 21:19 49:14 50:25 63:12 69:17 72:9 81:18 81:22 106:18 113:21 114:3,4,17 <b>women's</b> 61:12 <b>won't</b> 86:24,25 88:24 <b>word</b> 8:13 12:6 28:20 31:10 32:9 32:20 33:2 39:20	56:4,5 57:20 111:18 118:2,13 118:17,20 <b>words</b> 16:9 30:10 31:3 55:16 79:5 95:2,13 96:25 104:9 106:7 <b>word-for-word</b> 31:16 <b>work</b> 56:12 100:8 103:1 117:1 <b>worked</b> 56:10 116:14 <b>working</b> 56:25 87:25 91:19,24 <b>worse</b> 33:12 <b>wouldn't</b> 82:4 85:15 97:16,19 106:8 <b>wouldn't</b> 15:3,9 <b>write</b> 91:20 <b>written</b> 81:9,10 91:16 92:24 93:4 93:5,6 <b>wrong</b> 6:13 39:19 41:19 46:5 73:14 79:25 81:2,14,15 81:15 91:17 96:3 96:5 120:6,13 <b>wrote</b> 27:19 117:7	107:7,12,14 110:25 111:3,5 121:9,14,22 <b>yeah</b> 6:22 7:8 12:23 20:14,19,22 22:1 22:7 23:10,24 24:1 26:19,23 53:21 63:22 65:15 66:1 68:25 70:21 77:19 87:22 108:20 109:19 115:6 117:19 120:1,3,5 121:3 <b>year</b> 9:9 10:14 14:4 15:4 17:11 18:15 18:16 37:22 39:25 <b>years</b> 4:8 8:15 9:1,4 9:5,6 10:6,12,18 11:18 13:8,12 18:17,22 19:16,19 19:20 20:6 21:12 37:23,24 38:1 41:17 42:13 103:6 109:1 <b>yesterday</b> 4:6,11 5:23 6:2,5,7,10 16:8 25:18 26:14 26:18,24 27:5 28:19 29:17 34:2 35:7,9 45:18 46:22 49:8 52:4 56:22 59:10,12 62:5 67:5 78:16 80:7,19 81:5,17 87:24 91:4 98:3 99:2 102:12 106:11 108:16 109:24 110:21 111:18 112:14 113:18,24 115:20 116:2 119:1,3,12 <b>yielded</b> 73:10 <b>yields</b> 74:13 <b>you'd</b> 92:17,20 <b>you'll</b> 111:17 <b>you're</b> 84:24 93:9 100:20 101:9	102:15,16,23 103:20 107:16,22 109:25 110:4,15 120:2 <b>you've</b> 81:2 92:3 97:12 101:25,25 103:1 105:17 108:17
<hr/>				
<b>Z</b>				
<hr/>				
<b>Zealand</b> 68:10,12 69:10 <b>zero</b> 89:7,8,22 91:9 101:1,13 <b>Zoloft</b> 1:3 12:1,10 13:6,20,22,25 14:4,12 15:4,6,9 15:11,13,24,25 16:13,18,25 17:8 17:12 21:13,20 22:4 23:14 25:10 42:2 50:8 55:21 56:14,25 58:8 61:7,19 62:24 63:19 64:10,14 65:9,14 67:12,17 67:19 70:13 73:19 74:7 79:11,13 80:5 83:4,14 84:2 84:9 85:3,16,19 86:1 89:11 90:20 90:23 93:16 95:6 95:18 96:11,12 97:3,12 101:4,20 101:24 102:6,16 106:5 107:2 113:16,21,22 <b>zone</b> 45:12 <b>Zonies</b> 1:12 3:11,14 26:2 36:2,14 78:16				
<hr/>				
<b>0</b>				
<hr/>				
<b>0</b> 29:6,18 <b>0.02</b> 119:12 <b>0.5</b> 106:13 108:20 110:4				

<b>0.931</b> 65:13	<b>1800</b> 1:24	<b>259</b> 19:12,13	<b>8</b>
<b>00152</b> 122:21	<b>1801</b> 1:24	<b>27</b> 36:17	<b>82</b> 24:1
<b>051</b> 73:12	<b>19</b> 77:7	<b>27th</b> 39:3	<b>9</b>
<b>1</b>	<b>19103</b> 1:24	<b>3</b>	<b>9</b> 14:14
<b>1</b> 24:4 29:6,18,18	<b>1990</b> 6:23 7:4,5 8:2	<b>3</b> 2:3 19:6 33:19	<b>91</b> 6:25 9:12 10:12
29:19 32:14,15	<b>1991</b> 6:19 7:4,21,22	<b>3.3</b> 119:23	10:21 15:1
35:3 38:6,9,17	10:15,19 11:2	<b>3.8</b> 33:20	<b>92</b> 6:25
42:19 45:17,18	13:12,16	<b>30</b> 10:11 111:18	<b>93</b> 6:25 23:15
106:15,19 122:7	<b>1993</b> 16:1	<b>31</b> 36:2 110:24	<b>931</b> 67:19
<b>1-888-777-6690</b>	<b>1994</b> 17:3,7	111:9,13,14,21	<b>94</b> 6:25
1:25	<b>1996</b> 8:4,15 10:16	<b>33</b> 12:8,20	<b>95</b> 73:7,11
<b>1.0</b> 30:5,16,20	11:3,7 13:12,16	<b>352</b> 12:1,10 13:6	<b>96</b> 9:9,12 10:12,21
33:19 38:13 73:12	20:6	17:12	14:15 15:1 17:16
74:14	<b>1997</b> 8:7	<b>4</b>	17:18,22 18:22
<b>1.01</b> 38:17	<b>1998</b> 10:17	<b>40</b> 24:20	20:10
<b>1.02</b> 24:8 32:14	<b>2</b>	<b>44</b> 74:2 86:16,23	<b>97</b> 9:9 17:16,18,22
<b>1.05</b> 24:2,5	<b>2</b> 1:3 12:8,20 19:7	87:2 94:10	19:18 73:8
<b>1.07</b> 119:11	21:25 22:20 43:15	<b>45</b> 70:17,18,24,25	<b>98</b> 32:14,16
<b>1.08</b> 74:8 89:5	65:12 67:12	71:7 94:10	<b>99</b> 38:13
<b>1.1</b> 119:23	106:19 108:20	<b>46</b> 94:13	
<b>1.13</b> 23:13	110:4	<b>48</b> 24:9	
<b>1.2</b> 30:3,16,20 35:3	<b>2nd</b> 16:1	<b>5</b>	
45:9,17	<b>2.15</b> 24:9	<b>5</b> 21:25 22:18,19	
<b>1.28</b> 23:6	<b>2.3</b> 20:4,13,18,23	23:19,24 77:7	
<b>1.3</b> 48:1	21:19	<b>50</b> 20:15,18 104:12	
<b>1.35</b> 24:1,3 48:8	<b>2.39</b> 119:11	<b>51</b> 73:12	
<b>1.38</b> 23:15	<b>2:00</b> 121:17,21	<b>523</b> 15:22	
<b>1.4</b> 20:17	<b>2:12-md-02342-...</b>	<b>527</b> 18:22 19:12	
<b>1.65</b> 74:8	1:2	<b>57</b> 73:11 74:14	
<b>1.87</b> 119:11	<b>20</b> 77:22	<b>59</b> 73:8	
<b>1.9</b> 119:23	<b>2003</b> 8:4,15 18:22	<b>6</b>	
<b>10</b> 29:18	<b>2007</b> 4:18,20 6:19	<b>6</b> 70:15,16 71:1,12	
<b>10:05</b> 1:4	7:22 10:15,16,17	74:1 86:15,20,23	
<b>1007</b> 64:9	10:19	87:1,3 88:8 93:8	
<b>1011</b> 67:24 69:11	<b>2009</b> 8:7 19:19	94:6,19 111:9,15	
69:14	<b>2010</b> 4:18,18,20	111:21	
<b>103</b> 107:15	20:7,23	<b>68</b> 89:2 90:11	
<b>11:20</b> 66:13	<b>2013</b> 51:2 53:4	<b>7</b>	
<b>11:43</b> 66:13	<b>2014</b> 70:6 82:12	<b>7</b> 21:25 29:19	
<b>12:49</b> 1:4 121:23	83:16	107:16	
<b>128</b> 95:2	<b>2015</b> 1:3 20:2 36:18	<b>70</b> 74:8	
<b>13</b> 23:13	39:3 47:9,11 50:7	<b>76</b> 73:7,11 74:14	
<b>143</b> 95:13	50:11 74:23 122:7		
<b>15th</b> 39:2	<b>203</b> 53:1		
<b>154</b> 57:9	<b>22</b> 82:7		
<b>17</b> 13:8 17:3	<b>24</b> 90:24 92:2		